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               IN THE UNITED STATES DISTRICT COURT
               FOR THE NORTHERN DISTRICT OF OHIO
 2
                        EASTERN DIVISION
 3
    IN RE: NATIONAL PRESCRIPTION ) No. 17-md-2804
    OPIATE LITIGATION NO. 2804
                                     )
 5
   APPLIES TO ALL CASES
                                ) Hon. Dan A. Polster
6
7
         HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER
8
                    CONFIDENTIALITY REVIEW
9
              VIDEO DEPOSITION OF VALERIE KAISEN
10
                        January 18, 2019
11
                            9:39 a.m.
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           Reporter: John Arndt, CSR, CCR, RDR, CRR
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                      CSR No. 084-004605
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                          CCR No. 1186
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     sworn, and examined on January 18, 2019, at
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     East, Suite 1700, in the City of Cleveland, State of
 3
    Ohio, before John Arndt, a Certified Shorthand Reporter
    and Certified Court Reporter.
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1	INDEX OF INTERROGATION	
2	Examination by Mr. Faes	Page 9
	Examination by Mr. Maier	Page 270
3	Examination by Mr. Faes	Page 275
4		
	INDEX OF EXHIBITS	
5		
	Exhibit Teva-Kaisen-001	Page 11
6	(Notice of deposition)	
7	Exhibit Teva-Kaisen-002	Page 29
	(2016 performance review)	
8		
	Exhibit Teva-Kaisen-003	Page 40
9	(Chart)	
10	Exhibit Teva-Kaisen-004	Page 44
	(Approval package for Application Number	
11	20-747-S003)	
12	Exhibit Teva-Kaisen-005	Page 46
	(Risk Management Program)	
13	(TEVA_CHI_00049296 - TEVA_CHI_00049325)	
14	Exhibit Teva-Kaisen-006	Page 65
1.5	(Actiq Master Plan)	
15	(TEVA_CHI_00042757 - TEVA_CHI_00042817)	D
16	Exhibit Teva-Kaisen-007	Page 77
1 7	(Business Plan 2002 Val McGinley)	
17	(TEVA_MDL_A_10027910 - TEVA_MDL_A_10027915) Exhibit Teva-Kaisen-008	Daga 101
10	(2003 Actiq Marketing Plan)	Page 101
19	(TEVA_CHI_00042882 - TEVA_CHI_00042950)	
20	Exhibit Teva-Kaisen-009	Page 125
20	(2004 Actiq Marketing Plan)	rage 125
21	(TEVA_CHI_00042951 - TEVA_CHI_00043009)	
22	Exhibit Teva-Kaisen-010	Page 128
	(Department of Health and Human Services	1050 110
23	letter)	
	(TEVA_MDL_A_01584978 - TEVA_MDL_A_01584987)	
24		

1 2	INDEX OF EXHIBITS (CONTINUED)	
	Exhibit Teva-Kaisen-011	Page 140
3	(2005 Actiq Marketing Plan)	1030 110
	(TEVA_CHI_00043010 - TEVA_CHI_00043093)	
4	(<u>-</u>	
	Exhibit Teva-Kaisen-012	Page 159
5	(Guilty plea agreement)	
6	Exhibit Teva-Kaisen-013	Page 162
	(E-mail)	J
7	(TEVA_MDL_A_09069589 - TEVA_MDL_A_09069591)	
8	Exhibit Teva-Kaisen-014	Page 169
	(E-mail)	_
9	(TEVA_MDL_A_03571871 - TEVA_MDL_A_03571874)	
10	Exhibit Teva-Kaisen-015	Page 175
	(2005-2006 Marketing Plan)	
11	(TEVA_MDL_A_00368405 - TEVA_MDL_A_00368625)	
12	Exhibit Teva-Kaisen-016	Page 178
	(Marketing Plan 2007)	
13		
	Exhibit Teva-Kaisen-017	Page 183
14	(Ohio Valley Area Business Review)	
	(TEVA_MDL_A_00398748)	
15		
	Exhibit Teva-Kaisen-018	Page 190
16	(E-mail)	
	(TEVA_MDL_A_11198978 - TEVA_MDL_A_11198980)	
17		
	Exhibit Teva-Kaisen-019	Page 193
18	(GPE Actiq RMP Initial Off-Label Prescriber	
	Listing: July 2008)	
19	(TEVA_MDL_A_01485059 - TEVA_MDL_A_01485061)	
20	Exhibit Teva-Kaisen-020	Page 197
	(E-mail)	
21	(TEVA_MDL_A_10030379)	
22	Exhibit Teva-Kaisen-021	Page 202
	(Complaint)	
23		
	Exhibit Teva-Kaisen-022	Page 207
24	(Akron Beacon Journal article)	
1		

```
INDEX OF EXHIBITS (CONTINUED)
 1
     Exhibit Teva-Kaisen-023
                                                    Page 211
 3
    (Chart)
 4
    Exhibit Teva-Kaisen-024
                                                    Page 212
     (E-mail)
 5
     (TEVA_MDL_A_02072423 - TEVA_MDL_A_02072424)
     Exhibit Teva-Kaisen-025
 6
                                                    Page 216
     (Department of Justice press release)
 7
     Exhibit Teva-Kaisen-026
                                                    Page 223
 8
     (FAOs)
     (TEVA_MDL_A_00982822 - TEVA_MDL_A_00982836)
 9
     Exhibit Teva-Kaisen-027
                                                    Page 227
10
     (07-19-07 sales bulletin)
     (TEVA_MDL_A_00013847 - TEVA_MDL_A_00013856)
11
     Exhibit Teva-Kaisen-028
                                                    Page 231
12
    (04-15-08 sales bulletin)
     (TEVA_MDL_A_00739357)
13
     Exhibit Teva-Kaisen-029
                                                    Page 234
14
     (E-mail)
     (TEVA_MDL_A_06384299 - TEVA_MDL_A_06384302)
15
    Exhibit Teva-Kaisen-030
                                                    Page 238
    (Passion 4 Performance Impact)
16
17
     Exhibit Teva-Kaisen-031
                                                    Page 246
     (E-mail)
18
     (TEVA MDL A 09104614)
19
     Exhibit Teva-Kaisen-032
                                                    Page 249
     (Department of Health & Human Services letter)
20
     (TEVA_MDL_A_01251177 - TEVA_MDL_A_01251183)
21
     Exhibit Teva-Kaisen-033
                                                    Page 253
     (E-mail)
22
     (TEVA_MDL_A_01868221 - TEVA_MDL_A_01868222)
23
     Exhibit Teva-Kaisen-034
                                                    Page 256
     (Opiate Action Team RX prescribing guidelines)
24
```

```
1
                  INDEX OF EXHIBITS (CONTINUED)
 2
     Exhibit Teva-Kaisen-035
                                                     Page 256
     (Opioid morphine equivalent conversion
 3
     factors)
 4
    (TEVA_MDL_A_03702927)
    Exhibit Teva-Kaisen-036
 5
                                                     Page 260
    (E-mail)
    (TEVA MDL A 09098179)
 6
 7
    Exhibit Teva-Kaisen-037
                                                     Page 262
     (E-mail)
    (TEVA_MDL_A_01868209)
 8
    Exhibit Teva-Kaisen-038
                                                     Page 266
     (E-mail)
10
     (TEVA_MDL_A_01290215 - TEVA_MDL_A_01290216)
11
    Exhibit Teva-Kaisen-039
                                                     Page 270
     (E-mail)
     (TEVA_MDL_A_00979785 - TEVA_MDL_A_00979786)
12
13
                     (Exhibits are attached.)
14
15
16
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- 1 THE VIDEOGRAPHER: We are now on the
- 2 record. My name is Jacob Arndt. I am a videographer
- 3 for Golkow Litigation Services. Today's date is
- 4 January 18th, 2019, and the time is 9:39 AM. This
- 5 video deposition is being held in Cleveland, Ohio, In
- 6 Re: National Prescription Opiate Litigation for the
- 7 United States District Court, Northern District of
- 8 Ohio, Eastern Division. The deponent is Valerie
- 9 Kaisen. Will counsel please identify themselves?
- 10 MR. FAES: Andy Faes and Komal Jain for
- 11 plaintiffs.
- MR. MAIER: Jonathan Maier for the Teva
- 13 defendants.
- MS. FRANCIS: Tracy Francis from Porter,
- 15 Wright, Morris & Arthur for Cardinal Health.
- 16 MR. CALLAHAN: Luke Callahan with the
- 17 plaintiffs.
- 18 MR. BERG: Aaron Berg. I'm retained
- 19 counsel for Ms. Kaisen for the proceeding.
- THE VIDEOGRAPHER: Thank you. The court
- 21 reporter is John Arndt and will now swear in the
- 22 witness.

23

The witness, VALERIE KAISEN, first having been

- 1 duly sworn, testified as follows:
- 2 QUESTIONS BY MR. FAES:
- Q. Could you state your name for the record,
- 4 please?
- 5 A. Valerie Kaisen.
- 6 Q. Good morning, Ms. Kaisen. My name is Andy
- 7 Faes. I represent the plaintiffs in this litigation.
- 8 Do you understand that?
- 9 A. Yes.
- 10 Q. And do you understand that this lawsuit
- 11 has been brought on behalf of various states, counties,
- 12 and municipalities across the United States against
- 13 Teva and other defendants seeking to recover damages
- 14 for the public nuisance that is alleged to have been
- 15 caused by the opioid crisis?
- 16 A. Yes.
- Q. And what city do you currently live in?
- 18 A. Hinckley.
- 0. And that's in Ohio?
- A. Uh-huh.
- 21 Q. And we met briefly for the first time
- 22 yesterday; right?
- 23 A. Yes.
- Q. Have you ever given a deposition before

- 1 today?
- 2 A. No.
- Q. I'm sure your lawyer has briefed you on
- 4 the finer points of depositions, but I just want to ask
- 5 you to tell me -- if I ask you a question that you
- 6 don't understand today, will you let me know?
- 7 A. Yes.
- Q. And if I ask you a question and you answer
- 9 the question, I'm going to assume that you understood
- 10 the question that I asked. Is that fair enough?
- 11 A. Yes.
- 12 Q. I'm going to mark Exhibit Number 1 to your
- 13 deposition.
- 14 [Exhibit Teva-Kaisen-001
- marked for identification.]
- Q. And this is just the notice of deposition
- 17 that notes the time and date when this is occurring.
- 18 I'm not actually going to ask you any questions about
- 19 it. We just mark it for the record because that's our
- 20 favorite thing to do, like doctors taking your height,
- 21 weight, and blood pressure at the start of an exam, is
- 22 we mark the deposition notice. But that deposition
- 23 notice notes -- just notes that -- the time and place
- of your deposition. Now, you're actually here pursuant

- 1 to a subpoena that was served on you; right?
- 2 A. Yes.
- 3 Q. And are you represented by counsel in this
- 4 matter?
- 5 A. Yes.
- 6 Q. Who is your counsel?
- 7 A. Aaron Berg.
- 8 Q. So -- and Aaron Berg doesn't represent
- 9 Teva or Cephalon; right?
- 10 A. No.
- 11 Q. Did -- and did anyone from Teva reach out
- 12 to you or offer to represent you in this proceeding?
- 13 A. No.
- Q. What is your highest level of education?
- 15 A. Bachelor's of science.
- 16 Q. And where did you receive that from?
- 17 A. University of Massachusetts Amherst.
- Q. And what's it in? What's the bachelor's
- 19 of science in --
- 20 A. General and in clinical nutrition.
- Q. And who's your current employer?
- 22 A. Theratechnologies, Syneos.
- Q. And that's another job in the
- 24 pharmaceutical industry; right?

- 1 A. Yes.
- Q. And I understand your primary
- 3 responsibility right now is to sell or promote an HIV
- 4 medication. Is that right?
- 5 A. HIV medications, yes.
- 6 O. What medication is that?
- 7 A. Trogarzo and Egrifta.
- 8 O. And those are the two -- those are
- 9 currently the only two drugs that you're responsible
- 10 for?
- 11 A. Yes.
- 12 Q. How long were you with Cephalon, which
- 13 then later became Teva?
- 14 A. In total, 2001 to February 22nd, 2017.
- 15 Q. So well over 15 years; right?
- 16 A. Uh-huh.
- 17 Q. And for nearly the entire time that you
- 18 worked for Cephalon, which then later became Teva, from
- 19 2001 up until about the end of 2015, you were
- 20 responsible for -- at all times for promoting either
- 21 the Actiq product or the Fentora product; right?
- 22 A. Not the entire time.
- 23 O. From 2001 to 2015?
- A. Oh, to 2015. I'm sorry. If you say so.

- 1 They changed directions. Sorry. I don't recall.
- Q. But if I told you that the records
- 3 indicate that --
- 4 A. Yes. Yes.
- 5 Q. -- between 2001 through the end of 2015
- 6 you were responsible for promoting either Actiq and
- 7 then later Fentora --
- A. If the records show, yes.
- 9 Q. -- would that be consistent with your
- 10 memory?
- 11 A. Sure.
- 12 Q. And prior to joining Cephalon, you
- 13 actually had a great deal of experience in the
- 14 pharmaceutical industry; right?
- 15 A. Yes.
- 16 Q. Prior to -- where did you work prior to
- joining Cephalon and then later Teva?
- 18 A. I worked -- prior to Teva I worked for
- 19 Centocor, which is a division of Johnson & Johnson.
- 20 Q. And did you work from -- various companies
- 21 within Johnson & Johnson from approximately 1991 to
- 22 2001?
- 23 A. I also worked for Janssen.
- Q. And Janssen is a Johnson & Johnson

- 1 company; right?
- A. A division of Johnson & Johnson, yes. And
- 3 then I left to go to Boehringer Mannheim, and then they
- 4 were -- the drug was sold to J & J -- or promoted by J
- 5 & J.
- 6 Q. And during that time did you promote
- 7 some -- sell or promote some other drugs or products
- 8 that were indicated for pain management?
- 9 A. Could you clarify what time period you
- 10 want?
- 11 Q. Well, let me just ask it this way. Prior
- 12 to joining Cephalon and which later became Teva, did
- 13 you have some experience --
- 14 A. Yes.
- Q. -- selling or promoting --
- 16 A. Yes.
- 17 Q. -- drugs for pain management?
- 18 A. Yes.
- 19 Q. And just -- we're kind of talking to each
- other. Try to slow down and let me get the whole
- 21 question out; okay? And what drugs were those?
- 22 A. Duragesic. Alfenta, Sufenta. Amrix.
- Well, that was not before. I can't remember right now,
- 24 but yeah.

- Q. And Amrix -- actually, that's -- I think
- 2 you might have been mixed up. That's actually a
- 3 Cephalon product, right, not a Johnson & Johnson
- 4 product?
- 5 A. Yes.
- 6 Q. So you wouldn't have promoted that prior
- 7 to joining Cephalon?
- 8 A. No. No.
- 9 Q. And before Johnson & Johnson, you worked
- 10 for Astra Pharma from approximately 1985 to 1991; is
- 11 that right?
- 12 A. Yes. Uh-huh.
- Q. And what kind of products did you promote
- 14 for them?
- 15 A. For them I also -- Hemopad, which was a --
- 16 well, Hemopad and also injectable morphine. Alfenta,
- 17 Sufenta, or was that with J & J? I'm trying to think.
- 18 Gosh. You're going way back. Injectables. With Astra
- 19 and hemolytic.
- Q. And were any of those products for pain
- 21 management?
- 22 A. Yes.
- Q. Which ones?
- 24 A. The -- I'm trying to think. Xylocaine.

- 1 Sensorcaine. Those are local anesthetics. I can't
- 2 recall what else.
- Q. So you were first hired by Cephalon, and
- 4 that later became Teva, but you were first hired with
- 5 Cephalon in February of 2001?
- 6 A. Yes.
- 7 Q. That would have been when you actually
- 8 started; right?
- 9 A. Yes.
- 10 Q. And eventually that company became Teva?
- 11 A. Yes.
- 12 Q. And that happened in approximately 2011;
- 13 right?
- 14 A. Yes.
- Q. And you ultimately left Teva in 2017;
- 16 right?
- 17 A. Yes.
- 18 Q. And what were the circumstances of your
- 19 departure from Teva?
- 20 A. I was laid off.
- Q. What was the -- were you told a reason, or
- 22 what was the reason you were told why you were being
- laid off at that time in 2017?
- A. I don't recall, except downsizing.

- 1 Q. Now, during your time at Cephalon, you --
- 2 we talked a little bit about this already. You were
- 3 responsible for selling two different opioid narcotic
- 4 products; right?
- 5 A. Yes.
- 6 Q. And those two product -- the name of those
- 7 two products were Actiq and Fentora?
- 8 A. Yes.
- 9 Q. And prior to joining Cephalon, which later
- 10 became Teva, you had no experience -- you had
- 11 experience with pain medications, and we went through
- the names of some of those medications, but you had no
- 13 experience selling opioids or narcotics prior to
- 14 joining Cephalon; is that true?
- 15 A. No.
- 16 O. What --
- 17 A. Morphine with Astra. I said that. Yeah.
- 18 Q. Any other experience specifically selling
- opioids other than when you sold morphine for Astra?
- 20 A. Duragesic is a fentanyl patch with
- 21 Janssen.
- 22 Q. So prior --
- A. And Alfenta and Sufenta were used in
- 24 anesthesia in the OR.

- 1 Q. So prior to joining Cephalon and Teva you
- 2 actually had some experience in the industry --
- 3 A. Yes.
- 4 Q. -- selling opioids, and that included
- 5 selling a fentanyl patch, which is the same drug that's
- 6 in Actiq and Fentora? It's just a different delivery
- 7 system; right?
- 8 A. Yes.
- 9 Q. The patch is more of a gradual release
- 10 product where the Fentora and Actiq products are rapid
- 11 onset opioids; right?
- MR. MAIER: Objection. Form.
- 13 A. Yes.
- Q. (By Mr. Faes) So the first product that
- 15 you were -- one of the first products that you were
- 16 responsible for detailing and promoting when you became
- 17 an employee of Cephalon in February of 2001 was the
- 18 Actiq product; right?
- 19 A. Yes.
- 20 Q. And you would have been -- begun promoting
- 21 and selling that product immediately after your hiring
- 22 and training in February of 2001; right?
- 23 A. Yes.
- Q. And the Actiq product -- that was

- 1 essentially a fentanyl stick and sometimes it was
- 2 called a lollipop; right?
- A. Not out of our verbiage.
- 4 Q. But it was a fentanyl stick that went in
- 5 the mouth and was intended to be absorbed in the mouth;
- 6 right?
- 7 A. Yes.
- Q. And you came to learn that some people
- 9 would sometimes refer to it as a lollipop; right?
- 10 A. Yes.
- 11 Q. It wasn't officially company-sponsored
- jargon, but some people would call it that; right?
- 13 A. Yes.
- Q. When -- and when the Actiq product came on
- 15 the market when you joined in 2001, it was still a
- 16 relatively new product; right?
- 17 A. Yes.
- Q. And in 2001, when you started detailing
- 19 it, some people probably associated it with a prior
- 20 product which was a lozenge that was used prior to
- 21 surgery; is that right?
- 22 A. Yes.
- Q. Tell me about that product.
- A. I don't really recall, but it was -- I

- 1 never sold it, but I think the indication was for
- 2 pediatric prior to surgery or in surgery. I'm not
- 3 sure.
- 4 Q. And that was kind of an issue you
- 5 encountered early on as you needed to educate doctors
- on the difference between the fentanyl -- what some
- 7 people called the lollipop and this lozenge that had
- 8 been on the market for a while; right?
- 9 A. Yes.
- 10 MR. MAIER: Object to form.
- 11 Q. (By Mr. Faes) Because the -- and that's
- because the Actiq lollipop was certainly not intended
- 13 for children; right?
- MR. MAIER: Object to form.
- 15 A. It was not intended for children.
- 16 Q. (By Mr. Faes) And it was --
- 17 A. Never promoted that way.
- 18 Q. Right. Now, this Actiq product -- you
- 19 would have promoted or sold that right up until about
- the end of 2006; right?
- 21 A. If that's the time period you have.
- Q. Well, my question -- does that -- I mean,
- is that consistent with your memory that you would have
- 24 promoted the Actiq --

- 1 A. Okay.
- Q. -- right up until around the end of 2006?
- 3 A. Yes.
- 4 Q. And at the end of 2006, you would have
- 5 switched from -- end of 2006, early 2007, you would
- 6 have switched from promoting the Actiq product to
- 7 promoting the new Fentora product; right?
- 8 A. Yes.
- 9 Q. And the Fentora product was marketed by
- 10 the company as a new and improved replacement to the
- 11 Actiq product; right?
- MR. MAIER: Objection. Form.
- 13 A. Sorry. I heard something over there.
- Q. (By Mr. Faes) Yeah. Throughout the day,
- 15 counsel will object, and that's just for the record for
- later in case there's any issues. You can ignore that.
- 17 You can -- and just give him time to answer, but you
- 18 can ignore it and you can still answer the question.
- 19 The only time you can't answer a question is if your
- 20 counsel may --
- 21 A. Okay.
- 22 Q. -- direct you or advise you not to answer
- 23 a question. Okay?
- A. Okay. Please repeat the question, please.

- Q. Sure. The Actiq -- sorry. I'll start
- 2 over. And the Fentora product was marketed as a new
- 3 and improved replacement product to the Actiq; right?
- 4 MR. MAIER: Objection. Form.
- 5 A. Yes.
- 6 Q. (By Mr. Faes) And once you started
- 7 promoting Fentora, you stopped promoting Actiq; right?
- 8 A. Yes.
- 9 Q. Meaning you never promoted Actiq and
- 10 Fentora at the same time?
- 11 A. I don't recall.
- 12 Q. So -- and the Fentora product, instead of
- 13 being like a lollipop, these were actually buccal tabs,
- meaning they weren't intended to be swallowed; they
- were intended to be put in the cheek and dissolved in
- 16 the mouth; right?
- 17 A. Yes.
- THE VIDEOGRAPHER: Excuse me, ma'am.
- 19 [Discussion off the record.]
- 20 A. Could you repeat that question about the
- 21 buccal?
- Q. (By Mr. Faes) So the question was, and
- the Fentora product, instead of being like a lollipop,
- these were actually buccal tabs, meaning they weren't

- intended to be swallowed; they were intended to be
- 2 placed in the cheek and dissolved in the mouth; right?
- 3 A. Yes.
- Q. Now, one of the things that you -- well,
- 5 strike that. First let me ask you this. What was your
- 6 understanding of the reason why you -- you said you
- 7 couldn't remember if you ever promoted Actiq and
- 8 Fentora at the same time, but you would agree that you
- 9 stopped promoting Actiq shortly after the Fentora
- 10 product was launched; right?
- 11 A. Yes.
- 12 Q. What was the reason for that?
- 13 A. New product.
- Q. And it was marketed as an improved
- 15 product; right?
- 16 A. I don't recall.
- Q. Well, one of the things that you were told
- 18 to go out and promote and tell doctors about was an
- improvement of the product was the fact that unlike the
- 20 Actiq stick, the Fentora product didn't have any sugar;
- 21 right?
- 22 A. Yes.
- Q. And you also talked about the absorption
- 24 and the ease of use of the Fentora was better than the

- 1 Actiq stick; right?
- 2 MR. MAIER: Objection. Form.
- 3 A. Yes.
- 4 Q. (By Mr. Faes) You would talk about the
- 5 fact that it had a faster rapid onset, right -- the
- 6 Fentora product?
- 7 A. I understand the question.
- Q. Okay.
- 9 A. I'm just thinking about it.
- 10 Q. Okay.
- [Interruption by the reporter.]
- 12 A. Yeah, thank you. Because it's coming at
- 13 me pretty fast, so I'll need distinct -- repeat that
- 14 question.
- Q. (By Mr. Faes) Sure. You would talk about
- 16 the fact that the Fentora had a more rapid or faster
- onset than the Actiq product; right?
- 18 A. I don't recall.
- 19 Q. Well, let me put it another way. Maybe --
- whether or not you promoted it as having a faster or
- 21 more rapid onset specifically than the Actiq product,
- 22 that's certainly a product attribute of the Fentora
- 23 that you would have explained to doctors in part of
- 24 your promotion and detailing efforts; right?

- 1 A. Yes.
- 2 Q. And another thing that you would tell
- doctors is that by using the Fentora product a patient
- 4 could get ahead of the pain? That was one of the
- 5 benefits of the product; right?
- 6 MR. MAIER: Objection. Form.
- 7 A. I'm not going to answer that because I
- 8 don't remember.
- 9 Q. (By Mr. Faes) But you did sometimes hear
- 10 in meetings the -- I mean, you would go to various
- 11 marketing meetings and sales meetings with other
- salespeople and people in the marketing department;
- 13 right?
- 14 A. Yes.
- 15 Q. And you would hear sometimes the saying
- 16 that pain is pain?
- 17 A. Yes.
- 18 Q. Regardless of the source, pain is pain?
- 19 And is that something -- that's a saying or something
- 20 that you would use when you called on doctors promoting
- 21 the Actiq and Fentora product?
- MR. MAIER: Objection. Form.
- 23 A. I don't recall.
- Q. (By Mr. Faes) Now, other than noticing

- 1 the differences or improvements between the Fentora
- 2 product and the Actiq product, such as the fact that it
- 3 was -- the Fentora product had a lack of sugar and some
- 4 of the other stuff that we talked about, you would have
- 5 essentially used the same tools and strategies to sell
- 6 and promote the Fentora product that you did the --
- 7 that you used for the Actiq product; right?
- MR. MAIER: Objection. Form.
- 9 A. I don't recall.
- 10 Q. (By Mr. Faes) And you promoted Fentora
- all the way up until the end of 2015; right?
- 12 A. Yes.
- Q. And at the end of 2015, did the company
- 14 make a decision as a company to stop promoting Fentora
- 15 with its own internal sales force?
- 16 MR. MAIER: Objection. Foundation.
- 17 A. I was put to another sales force.
- 18 Q. (By Mr. Faes) Okay. But did you -- were
- 19 you made aware that as you were being transitioned to
- 20 another sales force that Teva was actually going to
- 21 bring in a third-party company to continue to mar --
- 22 A. I don't recall.
- Q. Let me get whole question out.
- A. Yeah.

- 1 Q. Do you remember as you were transitioned
- 2 to a new sales force that Teva was actually going to
- 3 bring in a third-party company to take over various
- 4 aspects of marketing and promoting the Fentora product?
- 5 MR. MAIER: Objection. Foundation.
- 6 A. I don't recall.
- 7 Q. (By Mr. Faes) Do you recall having to
- 8 meet or speak with anybody on a team when you were
- 9 taken off Fentora that would be taking over duties of
- 10 calling on physicians that you had previously called on
- 11 for Fentora?
- 12 A. I don't remember.
- 13 Q. In late two -- so you were moved from
- 14 Fentora to other products at the end of 2015?
- 15 A. Yes.
- Q. Do you remember towards the end of 2016
- 17 you being asked to once again promote Fentora products
- 18 for a short period of time? Do you remember that?
- 19 A. Yes.
- 20 Q. And what was the reason that you
- 21 understood that you were being asked to promote Fentora
- 22 again for a short time in 2016?
- A. Reach. Reach.
- Q. What does that mean?

- 1 A. Reaching the physicians that needed
- 2 information, so --
- 3 Q. Was --
- 4 A. Educational material.
- 5 Q. Was one of the reasons to help the company
- 6 exceed its financial objectives?
- 7 A. I don't recall.
- 8 MR. MAIER: Objection. Foundation.
- 9 [Discussion off the record.]
- 10 Q. (By Mr. Faes) Well, I'm going to hand you
- 11 what's been marked as Exhibit Number 2 to your
- deposition. I'm just going to write a tiny little 2 in
- 13 the corner here.
- 14 [Exhibit Teva-Kaisen-002
- marked for identification.]
- MR. FAES: So that will be yours and
- 17 that's a copy for counsel's --
- 18 MR. BERG: Okay. Thank you.
- MR. FAES: And this is 42, Mike.
- 20 A. Huh.
- 21 Q. (By Mr. Faes) So this is a document
- 22 entitled 2016 performance review for Valerie J. Kaisen.
- 23 Do you see that?
- 24 A. Yeah.

- Q. And if you look down towards the bottom
- 2 under goals for 2016, do you see where it states
- 3 started selling Fentora again to help the company
- 4 exceed financial objectives? Do you see that?
- 5 A. I do.
- 6 O. And that would have been -- this would
- 7 have been a document that you would have seen because
- 8 it was your performance review; right?
- 9 A. Hang on. Hang on.
- 10 Q. And actually if you look above it says --
- 11 actually appears to be your comments -- comments by
- 12 Valerie J. Kaisen. Do you see that above?
- 13 A. I do.
- Q. So this would have actually been something
- 15 that you wrote that you helped selling Fentora again in
- 16 2016 to help the company exceed financial objectives;
- 17 right?
- MR. MAIER: Objection. Form, foundation.
- 19 A. Yes.
- Q. (By Mr. Faes) So what did you mean by
- 21 that when you wrote it?
- 22 A. I don't recall.
- Q. Well, I mean, it's fair to say that you
- 24 probably wouldn't have written that in your comments

- 1 for your annual employee review --
- 2 A. Yeah.
- Q. -- if someone hadn't told you that that
- 4 was the reason why you were being asked to sell or
- 5 promote Fentora again; right?
- 6 MR. MAIER: Objection. Form, foundation.
- 7 A. Okay.
- 8 Q. (By Mr. Faes) Is that -- I mean, is that
- 9 true? That's probably not something you would have
- just come up on your own?
- 11 A. Yes.
- MR. MAIER: Same objection.
- 13 Q. (By Mr. Faes) So you -- so between Actiq
- 14 and Fentora, over 15 years -- 15-plus years, you
- 15 probably would have made literally thousands of sales
- 16 calls during that time period in Cleveland in the State
- of -- and the State of Ohio; right?
- 18 A. Yes.
- 19 Q. And I don't know that we talked about your
- 20 sales territory, but your sales territory at all times
- 21 between 2001 and 2015 included Cleveland and parts of
- 22 Ohio; right?
- 23 A. Yes.
- Q. And you would have kept notes of each time

- 1 that you made a sales call on a doctor; right?
 - 2 A. Notes?
 - 3 Q. Yeah, sales -- call notes?
- 4 MR. MAIER: Objection. Form.
- 5 A. We do not have call notes after a certain
- 6 time period.
- 7 Q. (By Mr. Faes) But there was a period of
- 8 time where you did have call notes --
- 9 A. Yes.
- 10 Q. -- or at least a call log; right?
- MR. MAIER: Objection. Form.
- 12 A. Call log? I don't know what that means.
- Q. (By Mr. Faes) Okay. At all times when
- 14 you were promoting Actiq and Fentora from 2001 to 2011,
- each time you made a visit to a doctor's office or a
- 16 doctor himself, you would have noted things like the
- date, the time, and the doctor, and when that occurred;
- 18 right?
- 19 A. Yes.
- Q. And that would happen every time; right?
- 21 You were trained to do that?
- 22 A. Yes.
- Q. And were you trained that that was
- 24 actually required by law that you kept a record of

- 1 that?
- 2 A. Yes.
- Q. And it was company policy that you do
- 4 that; right?
- 5 A. Yes.
- 6 Q. And for a time you would actually keep
- 7 notes of what transpired during a call; right?
- MR. MAIER: Objection. Form.
- 9 A. I don't understand the question.
- Q. (By Mr. Faes) Okay. Well, let me --
- 11 maybe this will help. Let me mark what's going to be
- 12 Exhibit Number 3 to your deposition.
- MR. FAES: Oh, she found it. Yeah.
- 14 A. Are you talking prior?
- Q. (By Mr. Faes) Well, let me just show you
- 16 the document.
- 17 A. Okay.
- Q. Maybe this will help you -- refresh your
- 19 memory. So this is Exhibit Number 3 to your
- 20 deposition, and this is a sampling of your -- what I
- 21 understand to be your call notes --
- 22 A. Put it up there.
- 23 Q. -- from approximately 2011 --
- MR. FAES: This is 7.1, Mike.

- 1 A. What's the date? Oh, yeah.
- Q. (By Mr. Faes) So if you look at this
- 3 document.
- 4 A. Yes.
- 5 Q. Like the first entry is -- it's got a call
- 6 date, 3-21-2001. It's got your name, which is -- at
- 7 that time would have been Valerie McGinley instead of
- 8 Valerie Kaisen; right?
- 9 A. Yes.
- 10 Q. It's got a rep ID. That's your rep ID;
- 11 right?
- 12 A. Yes.
- Q. Was your rep ID 1502 at all times when you
- were a rep, or do you know?
- 15 A. I don't recall.
- 16 Q. It's got a health care provider name,
- 17 which would be the doctor or doctor's office you called
- 18 on, right, and the first entry is -- for an example,
- 19 would be James Bressi; right?
- 20 A. Yes.
- Q. It's got his DEA number; right?
- 22 A. Yes.
- Q. And going acro -- it's got a city, state,
- 24 ZIP code, primary specialty; right?

- 1 A. Yeah.
- Q. And it's got the product you detailed?
- 3 A. Yes.
- 4 Q. Which on this particular document,
- 5 which -- all these are Actiq sales calls. And if you
- 6 want to look through the entire 20 pages, go ahead and
- 7 do that, but I believe these are all Actiq sales calls.
- A. I just have to look at the dates.
- 9 MR. FAES: Okay. While you're doing
- 10 that -- can you put that sticker over the 2 on Exhibit
- 11 2?
- 12 A. Yeah.
- Q. (By Mr. Faes) And on these call notes,
- 14 which are -- start early on after you were hired -- the
- 15 first one on this is March 27th of 2001, and that would
- 16 have been about a month after you were hired; right?
- 17 A. Yes.
- 18 Q. So this first entry probably would have
- 19 been one of your very first sales calls; right?
- 20 A. Yes.
- Q. And if you look at the first comment, at
- this time you were allowed to put a call comment in,
- 23 and on this one it, just for an example, says Dr.
- 24 Bressi on vacation. Had great meeting with his nurse

- 1 Jackie, who set me up breakfast Monday. His next lunch
- 2 was December 4th. Discussed breakthrough cancer pain,
- 3 BTcP --
- 4 A. Uh-huh.
- 5 Q. -- and the welcome kit she loved. She is
- 6 very impressed with the results of pain control of
- 7 Actiq. She is going to help. Right?
- 8 A. Yes.
- 9 Q. Now, at some time in 2006 or -- well,
- 10 strike that. Let me back up. Tell me at this time
- 11 when you first started, how was -- what was the method
- 12 that you used to enter call notes? Did you use a
- 13 computer? Did you write things out? Did you --
- 14 probably didn't have an iPad in 2001.
- 15 A. I don't recall when the change was.
- 16 Q. So -- but at this time in 2001 you were
- 17 allowed to --
- 18 A. We had paper copies. Yes.
- 19 Q. Let me start over.
- A. Thank you.
- Q. At this time in 2001 you had the ability
- 22 to enter a descriptive call comment describing what
- 23 happened during the call if you wanted to; right?
- 24 A. Yes.

- 1 Q. And at some point in 2006 or 2007, that
- 2 changed; right?
- 3 A. Yes.
- 4 Q. And at some point in 2006 and 2007, you
- 5 didn't have the ability to enter a call comment even if
- 6 you wanted to, such as the one you see in this exhibit
- 7 on the right-hand side; right?
- 8 MR. MAIER: Objection. Form.
- 9 A. Yes.
- 10 Q. (By Mr. Faes) And that was because the
- 11 way the call notes entry system was set up, you didn't
- even have an option to enter a free-form comment even
- if you wanted to; right?
- 14 A. Yes.
- Q. And all of the other fields -- they were
- 16 generally dropdown boxes, so you had to -- did you have
- 17 to select between certain options?
- 18 A. What year are you discussing?
- 19 Q. When the change occurred in 2006 or 2007.
- 20 A. Okay. Yes.
- 21 Q. From your experience, what was the reason
- 22 you understood why the company made that change in the
- 23 way that you were making call notes or sales logs --
- 24 whichever terminology you prefer?

- 1 MR. MAIER: Objection. Foundation.
- 2 A. Industry.
- Q. (By Mr. Faes) What do you --
- 4 A. Change.
- 5 Q. Industry changed. What do you mean by
- 6 that?
- 7 A. Due to certain -- we were told that we are
- 8 getting our call notes taken away due to the industry.
- 9 Q. And was one of the things that had changed
- in the industry that prompted this change the issue
- 11 that Purdue had had with some of their call notes from
- 12 their reps detailing the OxyContin product, which was
- 13 another opioid narcotic?
- MR. MAIER: Objection. Form, foundation.
- 15 A. I don't know what their decision was. I
- 16 just know what I might have thought.
- Q. (By Mr. Faes) Well, what was your
- 18 understanding at that time of the -- whether or not --
- 19 let me start over. What was your understanding at the
- 20 time of whether or not the situation with Purdue and
- 21 their notes that their sales reps had kept with
- 22 OxyContin was one of the reasons why -- the way these
- 23 call notes were changed?
- MR. MAIER: Objection. Form, foundation.

- 1 A. It was the way the industry was going.
- 2 I -- rephrase your question. I'm a little -- sorry.
- Q. (By Mr. Faes) Well, did you have an
- 4 understanding at that time, around the time these call
- 5 notes were being changed, that there were some folks at
- 6 Purdue that had been detailing OxyContin, which was
- 7 another opioid narcotic, that were getting in trouble
- 8 for having all kinds of crazy things written in their
- 9 call notes?
- 10 MR. MAIER: Objection. Form.
- 11 A. I wasn't at Purdue.
- Q. (By Mr. Faes) I know you weren't at
- 13 Purdue, but I'm just asking, did you have an
- 14 understanding at the time the company changed the sales
- 15 reps that that was going on -- the sales notes -- that
- 16 that was going on? I apologize.
- 17 A. In our company, the change was made
- 18 because of the industry. It's above my pay grade. I
- just do what I'm told, but you cannot -- how do I say
- 20 this? Everybody's interpretation is different.
- O. Sure. Sure. I understand.
- 22 A. So --
- 23 O. And I'm just asking for your
- 24 interpretation and your knowledge. Did you have

- 1 knowledge at that time --
- 2 A. That's not important --
- Q. -- that one of the things that was going
- 4 on in the industry was that folks who had worked for
- 5 Purdue and had detailed OxyContin at that time were
- 6 getting in trouble for all kinds of things that they
- 7 had written in their call notes when they were calling
- 8 on doctors for the OxyContin product?
- 9 MR. MAIER: Objection. Form, foundation.
- 10 A. Yes.
- 11 Q. (By Mr. Faes) And was it your
- 12 understanding or your belief at the time that that was
- one of the reasons why Teva decided to change the way
- 14 that call notes were kept and no longer have -- give
- 15 you the ability to enter a free-form call comment?
- A. My understanding, not my decision.
- Q. So was it your --
- 18 A. That was a corporate decision.
- 19 Q. Right. Was it your understanding that one
- of the reasons that they took away your ability to
- 21 enter a call comment as we see in Exhibit 3, is because
- of liability reasons?
- 23 [Exhibit Teva-Kaisen-003
- 24 marked for identification.

- 1 A. Yes.
- MR. MAIER: Objection. Form, foundation.
- Q. (By Mr. Faes) Now, during your employment
- 4 as a sales representative for Fentora and Actiq, you
- 5 would have been paid a base salary plus a bonus; right?
- 6 A. Yes.
- 7 Q. And that bonus would always be based on
- 8 some sales goal passed down by the company; right?
- 9 A. Yes.
- 10 Q. And the bonus would be based on whether
- 11 you met or exceeded those sales goals; right?
- 12 A. Yes.
- MR. MAIER: Objection. Form.
- Q. (By Mr. Faes) And the plan -- your salary
- 15 and bonus plan -- that would have changed from year to
- 16 year, but in general, your bonus would have represented
- 17 about 30 percent of your income and your base salary
- 18 would have represented about 70 percent of your income?
- 19 Does that sound consistent with your memory?
- MR. MAIER: Objection. Foundation.
- 21 A. There were times I didn't make bonus and
- 22 there were times I made bonus.
- Q. (By Mr. Faes) No, I understand that.
- A. So how are you going to get 30 percent?

- 1 Q. So let me see if I can phrase it another
- 2 way.
- 3 A. Thank you.
- 4 Q. If you made 100 percent of your bonus, in
- 5 general your bonus could represent up to 30 percent of
- 6 your income and your base salary would represent about
- 7 70 percent? Is that accurate?
- 8 A. Yes.
- 9 Q. And that was true more or less the entire
- time you detailed Actiq and Fentora from 2001 to 2015?
- 11 A. It was a changing goal. It changed.
- 12 Q. Right. I under -- and I understand that
- 13 the goals changed year by year and it fluctuated, but
- 14 I'm just asking in general that 70-30 percentages --
- 15 seven --
- 16 A. I don't remember exactly. I'm sorry.
- Q. Okay. Fair enough. So what I want to do
- 18 is kind of take you back to the beginning starting in
- 19 February 2001 when you first started and were trained
- 20 and put out in the field and selling Actiq. When you
- 21 were initially hired and sent out to the field, selling
- 22 and promoting Actiq would have been one of your primary
- 23 responsibilities; right?
- 24 A. Yes.

- 1 Q. And at some point during your initial
- 2 training with Cephalon, before you would have been sent
- 3 out into the field, you would have been made aware that
- 4 the Actiq product was subject to a risk map or risk
- 5 minimization plan which was required by the FDA as a
- 6 condition of being able to sell Fentora in the United
- 7 States; right?
- 8 MR. MAIER: Objection. Foundation.
- 9 A. What date?
- 10 Q. (By Mr. Faes) When you first started --
- 11 A. 2001?
- 12 Q. -- and were trained in 2001.
- 13 A. State that question again.
- Q. Sure. At some point during your initial
- 15 training with Cephalon, before you would have been sent
- out into the field, you would have been made aware and
- 17 trained that the Actiq product was subject to a risk
- 18 map or risk minimization plan, which was required by
- 19 the FDA as a condition of being able to sell Fentora in
- 20 the United States; right?
- 21 MR. MAIER: Same objection.
- 22 A. I guess I'm confused with your questioning
- because you're saying Actiq and then Fentora, or else
- 24 I'm missing it.

- 1 Q. (By Mr. Faes) Okay. That's -- you're
- 2 right. That's actually my fault. So at some point --
- 3 let me start over and restate the question. At some
- 4 point during your initial training with Cephalon,
- 5 before you would have been sent out into the field, you
- 6 would have been made aware and trained that the Actiq
- 7 product was subject to a risk map or risk minimization
- 8 plan, which was required by the FDA as a condition of
- 9 being able to sell Actig in the United States; right?
- MR. MAIER: Same objection.
- 11 A. I don't remember.
- 12 Q. (By Mr. Faes) Okay. Let me hand you,
- just to orient ourselves, what I'm marking as Exhibit
- 14 Number 4 to your deposition.
- 15 [Exhibit Teva-Kaisen-004]
- marked for identification.]
- 17 MR. FAES: And this is one, Mike. Yeah.
- 18 Q. (By Mr. Faes) So this is a document from
- 19 the FDA, and it's -- you see the trade name? It's for
- 20 Actiq?
- 21 A. Uh-huh.
- Q. And the approval date is March 26th of
- 23 1999. Do you see that?
- 24 A. Yes.

- Q. And if I can have you turn to the fourth
- 2 page in, which is a letter dated March 26th of 1999.
- 3 A. I was not with the company at that time --
- 4 for -- yeah. Okay.
- Q. And you see it's a letter from the FDA and
- 6 it's actually to Anesta, which would have been the
- 7 holder of Actiq at this time. Do you understand that?
- 8 A. Yes.
- 9 Q. You had an understanding that initially
- 10 Anesta was the company that had Actiq and then Cephalon
- 11 acquired Actiq from Anesta; right?
- 12 A. Yes.
- Q. And it just says dear Ms. Richards, please
- 14 refer to the supplemental new drug application, SNDA,
- dated February 10th, 1999, received February 19th,
- 16 1999, submitted under Section 505B of the Federal Food,
- 17 Drug, and Cosmetic Act for Actiq, oral transmucosal
- 18 fentanyl citrate, 200, 400, 600, 800, 1,200, and 1,600
- 19 milligrams. Is that milligrams?
- 20 A. Mic.
- Q. I'm sorry?
- 22 A. Yes. Mic. Mics.
- O. And those were -- mics?
- 24 A. Micrograms.

- Q. Micrograms. Okay. Thank you. So these
- were the microgram strengths that Actiq was available
- 3 in; right?
- 4 MR. MAIER: Objection. Form.
- 5 A. Yes.
- 6 O. (By Mr. Faes) And if you look down in the
- 7 third paragraph, I guess, from the bottom, it says for
- 8 future reference, revisions to the RMP, which means
- 9 risk map, must be submitted as a supplement that
- 10 requires our prior approval. Do you see that?
- 11 A. Yes.
- 12 Q. So this is the risk map, and I'm just
- 13 using this to orient you into time and space. I
- 14 realize you weren't there in 1999, but this document
- indicates that Actiq was approved in 1999 and it was
- 16 subject to a risk map that needed to be approved by the
- 17 FDA, and it needed to be approved if there was a change
- 18 or supplement to it; right?
- 19 MR. MAIER: Objection. Foundation.
- 20 A. Okay.
- Q. (By Mr. Faes) So you can set that aside,
- 22 and I'm going to hand you what's been marked as Exhibit
- Number 5 to your deposition.
- 24 [Exhibit Teva-Kaisen-005]

- 1 marked for identification.]
- 2 O. And this title is -- this document is
- 3 titled Actig risk manage -- sorry. Let me start over.
- 4 This document is titled Actiq risk management program,
- 5 August 1st, 2001. Do you see that?
- 6 A. Uh-huh.
- 7 Q. And at this time you would have been with
- 8 the company; right?
- 9 A. Yes.
- 10 Q. So this would have been one of the risk
- 11 maps that would have been in effect while you were
- detailing and promoting Actiq; right?
- 13 A. I don't remember.
- Q. Okay. Well, let's go through it, and I
- just want to ask some questions about whether or not
- 16 you remember parts of this document or whether you were
- 17 trained or given information --
- 18 A. Okay.
- 19 Q. -- by your superiors at the company about
- 20 any of this document. Okay?
- A. Yeah.
- 22 Q. So if you turn into the first page of
- this, it says under introduction the Actiq risk
- 24 minimization program, RMP, has been designed to address

- 1 three key potential risk situations. Did I say Page 1?
- 2 I mean Page 5.
- A. This is Page 1 up here. Sorry.
- 4 Q. So let me start over because you weren't
- 5 there yet.
- 6 A. Thank you.
- 7 Q. Are you there?
- 8 A. Yeah.
- 9 Q. So if you look at the introduction section
- of this document, under introduction it says the Actiq
- 11 risk management program, RMP, has been designed to
- 12 address three key potential risk situations, and it has
- 13 three main things that it's designed to address, right,
- 14 and the second of the three is improper patient
- 15 selection, prescriptions to and usage by
- 16 opioid-nontolerant patients; right?
- 17 A. Yes.
- 18 Q. And if you look down at the bottom of this
- 19 page starting at key messages for the RMP, which is the
- 20 risk management program, it says there are several key
- 21 messages repeated throughout the RMP which are listed
- 22 below. For the balance of the document these messages
- will be referenced simply as child safety, proper
- 24 patient selection, and prevention of diversion or abuse

- 1 messages. Do you see that?
- 2 A. I do.
- Q. And then if you go to the following page
- 4 on Page 6, under proper patient selection, messages, it
- 5 says Actiq is specifically contraindicated for use in
- 6 opioid-nontolerant patients and Actiq is specifically
- 7 contraindicated for acute postoperative pain, and the
- 8 third one down is Actiq is specifically indicated
- 9 solely for the treatment of breakthrough cancer pain in
- 10 chronic opioid-tolerant cancer patients; right?
- 11 A. Yes.
- 12 Q. So is this information that you would have
- 13 been trained on before you were sent out into the field
- 14 as a sales representative who was promoting and
- 15 detailing Actig?
- 16 A. Yes.
- 17 Q. And below it says prevention and diversion
- abuse messages, Actiq may be habit forming.
- 19 A. Trying to catch up. Hang on, please.
- 20 This is not catching up. Okay. Can you start over?
- 21 Q. Sure. Down below it says prevention and
- 22 diversion -- prevention of diversion and abuse
- 23 messages, Actiq may be habit forming.
- A. Yeah.

- 1 Q. That's something else you were trained
- 2 on --
- 3 A. Yes.
- 4 Q. -- before being sent out into the field
- 5 to detail or promote Actiq; right?
- 6 A. Yes.
- 7 Q. And if you -- let's go onto Page 11. On
- 8 this page down towards the bottom, starting with the
- 9 bottom paragraph, it says Actiq --
- MR. BERG: Hold on.
- 11 A. It's not the same time period here, so --
- Q. (By Mr. Faes) I'm sorry?
- A. Do we have it now? We're good?
- Q. Oh, we're just getting the screens synced
- 15 up.
- 16 A. You're going and this isn't --
- 17 Q. Got it. Are we there now?
- 18 A. Start over, please.
- 19 Q. Sure. So if you --
- MR. BERG: Here. Let's just locate it.
- Q. (By Mr. Faes) So if you look on Page 11
- of this 2001 risk map, down towards the bottom it
- 23 states Actiq is intended to be used only --
- A. Yeah.

- Q. -- in the care of cancer patients and
- only by oncologists and pain specialists who are
- 3 knowledgeable and skilled in the use of Schedule II
- 4 opioids to treat cancer pain?
- 5 A. Yes.
- 6 O. Is that something you were trained on
- 7 before you were sent out into the field, that it was
- 8 only to be used by oncologists and pain specialists?
- 9 A. Yes.
- 10 Q. And this would have been direction given
- 11 to you by your trainers and superiors at the company
- 12 that you should follow the guidelines set forth in this
- 13 risk map; right?
- MR. MAIER: Objection. Form.
- 15 A. Yes.
- 16 Q. (By Mr. Faes) And did they train you that
- these guidelines were required by the FDA as a
- 18 condition of keeping the product on the market?
- 19 MR. MAIER: Objection. Form.
- 20 A. I don't know about the market, but this is
- 21 what we were trained in.
- 22 Q. (By Mr. Faes) Okay. Well, regardless,
- 23 you would agree that you were trained that it was
- company policy to adhere to these guidelines; right?

- 1 A. Yes.
- Q. If you turn to Page 12 of this, under 4.1,
- 3 key message points. It states the education of
- 4 physicians, nurses, pharmacies, caregivers, and
- 5 patients on the safe use of Actiq is an integral part
- of the Actiq risk management program. These
- 7 educational messages are drawn directly from the Actiq
- 8 package insert. These key safety messages, which have
- 9 been described earlier in Section 1.1 of this RMP,
- 10 include -- and the third bullet point down is
- 11 prevention of diversion and abuse messages. Do you see
- 12 that?
- 13 A. Yes.
- Q. And that's something that you were trained
- on by your superiors prior to going out into the field
- 16 and promoting Actiq; right?
- 17 A. Yes.
- 18 Q. And you understood that it was company
- 19 policy to adhere to these guidelines; right?
- 20 A. Yes.
- 21 O. At all times --
- 22 A. Yes.
- Q. -- when you were promoting Actiq? If you
- turn to Page 13 of this document under 4.4,

- 1 publications.
- 2 A. I need a break.
- 3 Q. Yeah, I hear you need a break. I got like
- 4 three more questions in this document and then we'll
- 5 take a break; okay?
- 6 A. Thank you.
- 7 Q. Unless you need to now.
- 8 A. No, no, no.
- 9 Q. I told you you could take a break anytime
- 10 you want, but -- so under this Section 4.4,
- 11 publications, it states manuscripts will be submitted
- to peer-reviewed journals for consideration. They will
- include messages that reinforce elements of this RMP;
- 14 right?
- 15 A. Okay.
- 16 Q. Is that something that you were trained on
- that the company would do prior to going out into the
- 18 field to sell Actiq?
- 19 A. I don't remember.
- Q. Did you understand that it was company
- 21 policy to -- during your time selling and promoting
- 22 Actiq that manuscripts would be submitted to
- peer-reviewed journals for consideration that include
- 24 messages that reinforce elements of the RMP?

- 1 MR. MAIER: Objection. Foundation.
- 2 A. I don't remember.
- Q. (By Mr. Faes) If you turn to Page 17 of
- 4 this document. Strike that. Turn to page 16 of this
- 5 document. And you see there's a section entitled the
- 6 oncology sales specialist.
- 7 A. Yeah.
- Q. And it says, at least as part of the risk
- 9 map -- this risk map, it says that full-time oncology
- 10 sales specialists have been placed in the field to
- 11 personally call on the target audience. The oncology
- sales specialists are the primary day-to-day link of
- 13 the physicians, nurses, and pharmacists who will be
- 14 using the product. The oncology sales specialists will
- 15 play a key role in implementing the RMP. Do you see
- 16 that?
- 17 A. I do.
- 18 Q. During your time at Cephalon in 2001 --
- 19 August of 2001 and 2002 -- did Cephalon in fact have
- 20 full-time oncology sales specialists?
- MR. MAIER: Objection. Form, foundation.
- 22 A. I don't remember.
- Q. (By Mr. Faes) Were you aware of any
- 24 full-time oncology sales specialists?

- 1 MR. MAIER: Objection. Form.
- 2 A. I don't remember.
- Q. (By Mr. Faes) Were you considered a
- 4 full-time oncology sales specialist, or were you
- 5 considered something different?
- 6 A. I really don't remember what my title was.
- 7 It changed so much.
- 8 Q. Was your initial -- do you recall if your
- 9 initial title when you were hired was PCS sales
- 10 specialist? Would that be consistent with your memory?
- 11 A. That's a primary care specialist -- PCP.
- 12 What is your definition of that? What is it?
- Q. Well, let me ask it another way.
- 14 A. Give me the acronym definition.
- Q. At any time during your employment with
- 16 Cephalon --
- 17 A. Cephalon.
- 18 Q. Cephalon and Teva. Let me ask it another
- 19 way. When I -- for the rest of the day, if I say the
- 20 company, can we agree that I'm talking about Cephalon
- 21 and then Teva? Because it was essentially -- from your
- 22 perspective it was the same employer the whole time;
- 23 right?
- A. I'm not going to agree with that. I'd

- 1 like you to keep them separated --
- 2 Q. Okay.
- 3 A. -- because they were two separate --
- 4 Q. Fair enough. At any time during your
- 5 employment with Cephalon or Teva, were you -- did you
- 6 ever have the word oncology or oncology specialist in
- 7 your title?
- A. I don't remember.
- 9 Q. Well, let's turn to Page 17 of this and
- 10 look at some of the duties of the oncology sales
- 11 specialist.
- 12 A. Okay.
- 13 Q. Upon hiring, each specialist will receive
- 14 a letter outlining his responsibilities. This letter
- will stress the requirement to limit the promotion of
- 16 Actiq to the approved indication, discourage off-label
- 17 use, direct the specialist to promote only to the
- 18 target audiences, describe the serious consequences of
- 19 violating this policy, and reinforce the three key
- 20 messages of the risk map. Do you see that?
- 21 A. I do.
- 22 Q. Was one of your job responsibilities ever
- 23 to specifically discourage off-label use?
- MR. MAIER: Objection. Form.

- 1 A. Yes.
- Q. (By Mr. Faes) And how did you do that?
- 3 A. Well, they asked -- well, I would just --
- 4 I'd go in to a physician. The indication is for
- 5 breakthrough cancer pain. And if they asked me about
- 6 something else, I would say the indication is for
- 7 breakthrough cancer pain, and if you'd like to have any
- 8 more information, fill out a medical information
- 9 request.
- 10 Q. But that was -- you'd agree with me that
- 11 that was -- strike that. You would agree with me that
- 12 that is the limit of what the company trained you to do
- in order to discourage off-label use, is to simply
- 14 repeat what the indication to the doctor -- strike
- 15 that. You'd agree with me that that is the limit of
- 16 what the company trained you to do to discourage
- off-label use of Actiq, is to simply restate to the
- 18 physician, if he was using it off-label, what the
- 19 indication was?
- MR. MAIER: Objection. Form, foundation.
- 21 A. That was part of it, but I don't remember.
- Q. (By Mr. Faes) Well, I mean, you would
- agree with me that you generally didn't feel like it
- 24 was appropriate for you to get between the doctor and

- 1 the patient in his prescribing decisions; right?
- MR. MAIER: Objection. Form.
- 3 A. I was never privy to be there. I was
- 4 never -- I never knew what the physician was writing
- 5 for an individual patient. Is that what you're getting
- 6 at?
- 7 Q. (By Mr. Faes) So my question is simply,
- 8 you would agree with me --
- 9 A. I need a break.
- 10 Q. -- that you generally didn't feel like it
- 11 was appropriate for you to get in between the doctor
- 12 and his patients in his prescribing decisions? It
- 13 wasn't part of your job --
- 14 A. Right.
- 15 Q. -- to second-quess his decisions or
- 16 discourage him from what he thought was appropriate;
- 17 right?
- 18 MR. MAIER: Objection. Form.
- 19 A. I guess no. I mean, I stated the
- 20 indication. I would not get in between their
- 21 prescribing, no, but I would state the indication.
- Q. (By Mr. Faes) Right. And that was the
- limit of what you would do to discourage the doctor
- 24 from writing it off-label, is to restate the

- 1 indication; right?
- 2 MR. MAIER: Objection. Form.
- A. I can't remember. I'm sorry.
- 4 Q. (By Mr. Faes) Okay.
- 5 MR. MAIER: Break?
- 6 A. I need a break.
- 7 MR. MAIER: All right. We'll take a
- 8 break.
- 9 MR. FAES: Okay. Let's take a break.
- 10 A. Thank you.
- 11 THE VIDEOGRAPHER: We are going off the
- 12 record at 10:41 AM.
- [A brief recess was taken.]
- 14 THE VIDEOGRAPHER: We are back on the
- 15 record at 10:59 AM.
- Q. (By Mr. Faes) Ms. Kaisen, we're back on
- 17 the record after a short break. Are you ready to
- 18 proceed?
- 19 A. Yes.
- 20 Q. So we were talking before the break about
- 21 the oncology sales specialist referenced in Page 16 of
- 22 the August 2001 risk map. If the records reflect that
- your position at this time in August of 2001 was that
- you were a PCS sales specialist or pain care

- 1 specialist -- sales specialist, would you have any
- 2 reason to disagree with that?
- 3 A. No.
- Q. During this time in 2001 and 2002, did
- 5 you -- do you recall ever meeting with anyone else who
- 6 was considered an oncology sales specialist at
- 7 Cephalon?
- MR. MAIER: Objection. Form.
- 9 A. I don't remember.
- 10 Q. (By Mr. Faes) Do you recall -- well,
- 11 strike that. Was there anyone else at Cephalon that
- 12 you were aware of whose job it was to discuss and
- 13 discourage off-label use of Actiq with physicians other
- 14 than yourself?
- MR. MAIER: Objection. Form, foundation.
- 16 A. I don't remember.
- Q. (By Mr. Faes) If you can turn to Page 27
- of this risk map. Under off-label usage, individual
- 19 prescribers, it states whenever a problem of off-label
- 20 usage becomes known and individual prescribers are
- 21 identified, the following activities will take place.
- 22 And the first activity is that a letter from Cephalon,
- 23 Inc.'s medical department will be sent to all
- identified prescribers to emphasize the approved

- 1 indication and appropriate patient selection. Do you
- 2 see that?
- 3 A. I do.
- 4 Q. Were you trained by your superiors that
- 5 this was something that would go on at Cephalon
- 6 whenever a problem of off-label usage becomes known?
- 7 MR. MAIER: Objection. Form.
- 8 A. I don't remember.
- 9 Q. (By Mr. Faes) When you were a sales rep
- 10 at Cephalon, do you remember ever participating or
- 11 being involved in any kind of a program whereby -- when
- off-label -- a problem with off-label usage became
- 13 known, individual prescribers would be sent a letter
- 14 emphasizing the approved indication?
- MR. MAIER: Objection. Form.
- 16 A. I don't remember.
- 17 Q. (By Mr. Faes) But you would agree with me
- 18 that part of your responsibilities as a sales rep would
- 19 have been to be familiar with this Actiq risk map,
- 20 including the goals and objectives of the risk map;
- 21 right?
- MR. MAIER: Object to form.
- Q. (By Mr. Faes) I realize it was a long
- 24 time ago.

- 1 A. I don't remember. 18 years, 19 years ago.
- Q. But that is something you were trained on,
- 3 that according to this risk map, Actiq should only be
- 4 used in opioid-tolerant patients with cancer; right?
- 5 A. Yes.
- 6 O. And you were trained on the same thing for
- 7 Fentora when it came out and replaced Actiq as the
- 8 focus of your selling and promotional activities;
- 9 right?
- 10 A. Could you repeat that? Not the first
- 11 part; the second part. I was thinking about the first
- 12 part.
- Q. You were trained on the same thing,
- 14 meaning that according to the risk map, Fentora should
- only be used in opioid-tolerant patients with cancer
- 16 when it came out and replaced Actiq as the focus of
- 17 your selling and promotional activities; right?
- 18 A. Yes.
- MR. MAIER: Object to form.
- 20 O. (By Mr. Faes) Breakthrough pain without
- 21 cancer was not indicated for Actiq or Fentora at any
- time when you worked for Cephalon and Teva; right?
- A. It was not indicated.
- Q. And you would agree with me that marketing

- 1 or promoting Actiq or Fentora for breakthrough pain
- 2 without cancer would be off-label; right?
- 3 A. Yes.
- 4 Q. And you understood that marketing
- 5 off-label was illegal; right?
- 6 A. Yes.
- 7 Q. And you were instructed and trained not to
- 8 do that; right?
- 9 A. Yes.
- 10 Q. Now, you understand that every year or so,
- 11 Cephalon and later Teva would come out with marketing
- 12 plans for the Actiq and Fentora products; right?
- 13 A. Yes.
- MR. MAIER: Objection. Form.
- Q. (By Mr. Faes) And those marketing plans
- were put together by the marketing department; right?
- 17 A. Yes.
- 18 Q. And they contained strategies and tactics
- 19 for successfully promoting and selling both Actiq and
- 20 later Fentora; right?
- 21 MR. MAIER: Objection. Form.
- 22 A. Yes.
- Q. (By Mr. Faes) And these were national
- 24 marketing plans, meaning they were intended to be used

- 1 all over the United States; right?
- 2 A. Yes.
- Q. And that would include the territory that
- 4 you were responsible, which included at all times
- 5 Cleveland and part of Ohio; right?
- 6 A. Yes.
- 7 Q. And those marketing -- as a sales
- 8 representative responsible for promoting and selling
- 9 Actiq and Fentora, those marketing plans would have
- 10 been shared with you; right?
- 11 A. Yes.
- 12 Q. And that's because as a sales
- 13 representative, you were the person in the trenches, so
- 14 to speak, meaning you were one of the persons
- 15 responsible for carrying out various aspects of those
- 16 plans in the field; right?
- 17 A. Yes.
- 18 Q. And you recall that many of these early
- marketing plans for Actiq had a bell on the cover;
- 20 right?
- 21 A. Yes.
- Q. And that bell became kind of a marketing
- 23 symbol within the company for the Actiq product; right?
- 24 A. Yes.

- 1 Q. And why was that? Explain to me what the
- 2 bell represented.
- 3 A. I'm thinking, and I -- you can get pain
- 4 relief on demand?
- 5 Q. Right. And so essentially it was kind
- 6 of -- it was a little bell. Ding the bell, get relief
- 7 on demand; right?
- A. (Nodding "yes.")
- 9 MR. MAIER: Objection. Form.
- 10 Q. (By Mr. Faes) And that was essentially
- 11 what Actiq was for, was for somebody who was having a
- 12 breakthrough onset of pain and was already on an opioid
- and needed to get through that breakthrough pain;
- 14 right?
- 15 A. Yes.
- 16 Q. So I'm going to hand you what's been
- 17 marked as Exhibit Number -- I'm going to hand you
- 18 what's been marked as Exhibit Number 6 to your
- 19 deposition.
- 20 [Exhibit Teva-Kaisen-006
- 21 marked for identification.]
- 22 A. Oh. I'm taking your stickers.
- Q. Yeah, I'm trying to keep my stickers
- 24 straight so I don't lose them again.

- 1 A. I'm taking your stickers.
- 2 O. And this a document entitled -- I know
- 3 this is thick. I'm not going to go through all of it
- 4 with you. Don't worry.
- 5 A. No.
- 6 Q. This is a document entitled Actiq master
- 7 plan. Do you see that? And it's dated November 16th,
- 8 2000. Do you see that?
- 9 A. Prior to my employment.
- MR. BERG: Just yes.
- 11 A. Yes.
- 12 Q. (By Mr. Faes) So if I can have you just
- 13 turn to Page 2 of this document.
- 14 A. Put it up there.
- MR. FAES: I think it's 3 for you, Mike.
- 16 A. It's easier for me up there. There's --
- 17 oh, there it is. 3. 2. 2. Okay.
- 18 Q. (By Mr. Faes) So if you see under
- 19 Paragraph 4 --
- MR. BERG: Might be easier just to --
- 21 A. It's actually easier here.
- Q. (By Mr. Faes) If you see on Paragraph 4
- of this, it states that feedback from the field
- indicates that oncologists simply aren't treating that

- 1 many people for breakthrough cancer pain. Do you see
- 2 that?
- 3 A. Yes.
- 4 Q. And as you stated, this predates your
- 5 employment, but is this information that would have
- 6 been communicated to you upon your initial training on
- 7 Actiq when you joined Cephalon?
- MR. MAIER: Objection. Form, foundation.
- 9 A. Don't remember.
- 10 Q. (By Mr. Faes) Is it something that you
- 11 came to understand during the course of your employment
- 12 with Cephalon?
- 13 A. Yes.
- 14 Q. If you go down to Paragraph 5 it states
- that among physicians who are prescribing Actiq,
- 16 activity is skewing increasingly towards the
- 17 nononcologists. Units written by oncologists now
- 18 represent just 16 percent of total product usage, with
- 19 48 percent coming from pain management specialists. Do
- 20 you see that?
- 21 A. I see it.
- 22 Q. Is that statement consistent with your
- 23 understanding of what the approximate breakdown was
- 24 between oncologists and pain management specialists

- 1 when you were working at Cephalon?
- MR. MAIER: Objection. Form, foundation.
- 3 Q. (By Mr. Faes) In early 2001, 2002?
- 4 MR. MAIER: Same objection.
- 5 A. I don't know.
- 6 O. (By Mr. Faes) Do you have any reason as
- 7 you sit here today to disagree with that?
- 8 A. If it's written it's written.
- 9 Q. Okay. And if you go to Paragraph 6, it
- 10 states we believe that the pain management specialist
- is likely to be a more aggressive writer and adopter of
- 12 Actiq. Do you see that?
- A. Uh-huh.
- 14 Q. Is that something you were trained on or
- 15 was communicated to you within your first few years as
- 16 a sales representative for Actiq?
- 17 MR. MAIER: Objection. Form.
- 18 A. I don't remember.
- 19 Q. (By Mr. Faes) Was that something that you
- 20 came to understand during the course of your employment
- 21 with Cephalon when you were promoting Actiq?
- MR. MAIER: Objection. Form.
- 23 A. Yes.
- Q. (By Mr. Faes) And if you go to the last

- 1 symptom of this paragraph, it states in addition, from
- 2 a business perspective, these physicians tend to have
- 3 patients who are more likely to be truly chronic with
- 4 many years of potential usage of the product either for
- 5 breakthrough pain or generally for other chronic pain
- 6 conditions. Do you see that?
- 7 A. I see it.
- 8 Q. Is that information that was shared with
- 9 you from the marketing department during your time
- 10 selling Actiq?
- MR. MAIER: Objection.
- 12 A. I don't remember.
- 13 Q. (By Mr. Faes) Is that something that you
- 14 came to understand was true when you were promoting and
- 15 selling Actiq?
- 16 A. No comment. Rephrase.
- 17 Q. Did you come to understand when you were a
- 18 sales representative promoting and detailing Actiq that
- 19 the pain -- from a business perspective, the pain
- 20 management specialists tend to have patients who are
- 21 more likely to be truly chronic with many years of
- 22 potential usage of the product either for breakthrough
- pain or more generally for other chronic pain
- 24 conditions?

- 1 MR. MAIER: Objection. Form, foundation.
- 2 A. I don't like the way that question is --
- 3 I'm sorry. I don't know how to answer that.
- 4 Q. (By Mr. Faes) So is it fair to say you
- 5 can't answer that question yes or no as you sit here
- 6 today?
- 7 A. Yes. I can't answer it. Don't remember.
- Q. What do you remember about that?
- 9 MR. MAIER: Objection. Form.
- 10 A. Question?
- 11 Q. (By Mr. Faes) Yes. What do you remember
- 12 about whether or not from a business perspective pain
- 13 management specialists tend to have patients who are
- 14 more likely to be truly chronic with many years of
- potential usage of the product?
- 16 A. What I do remember is the oncologists at
- 17 the time were deferring their patients to pain
- 18 management because they didn't have the expertise or
- 19 the environment -- it was making them uncomfortable, so
- they would refer to the pain specialists, and that's
- 21 why we went to the pain specialists. This is a
- 22 little --
- Q. But you would agree with me that pain
- 24 specialists in general are more likely to have

- 1 noncancer patients like oncologists; right?
- 2 A. Yes.
- MR. MAIER: Objection. Form.
- 4 Q. And a person who does not have cancer --
- 5 terminal cancer is much more likely to have many
- 6 potential years of use with any product; right?
- 7 MR. MAIER: Objection. Form, foundation.
- 8 A. I quess.
- 9 Q. (By Mr. Faes) If you go to the top of
- 10 Page 3, which is the next page in this document, under
- 11 strategic recommendations. It states based on our
- 12 experience to date with Actiq, we believe it can
- 13 continue to grow aggressively into 2001 and beyond,
- 14 expanding the target physician and patient population
- to allow penetration of the broad chronic pain market.
- 16 This should be the driver of all activities associated
- 17 with Actiq in 2001 -- marketing, clinical, regulatory,
- 18 and operations. Do you see that?
- A. Uh-huh.
- 20 O. Is that information that was given by the
- 21 marketing department to you while you were a sales
- 22 representative detailing and promoting Actiq?
- MR. MAIER: Objection. Form.
- 24 A. I don't remember.

- Q. (By Mr. Faes) Did you come to understand
- 2 that this was true while you were a sales
- 3 representative promoting and detailing Actiq?
- 4 MR. MAIER: Objection. Form.
- 5 A. For the indication of breakthrough cancer
- 6 pain, period.
- 7 Q. (By Mr. Faes) So with the
- 8 qualification -- with that qualification, you did
- 9 understand this to be true?
- 10 MR. MAIER: Objection. Form.
- 11 A. I guess I'm confused by your questioning.
- 12 I'm sorry. Rephrase.
- 13 Q. (By Mr. Faes) Okay. So my question is,
- 14 when you were a sales representative for Cephalon
- detailing Actiq, did you come to understand that based
- on the company's experience to date with Actiq in 2001
- 17 that the company believed it could continue to grow
- 18 aggressively into the years beyond by expanding the
- 19 target physician and patient population to allow
- 20 penetration of the broad chronic pain market?
- MR. MAIER: Objection. Form, foundation.
- 22 A. I don't remember. I don't like the way
- 23 he's phrasing it. Sorry.
- Q. (By Mr. Faes) So if you go down to --

- 1 it's the middle of the page starting with bring
- 2 existing clinical programs. So under strategic
- 3 recommendations it states that one of them is to bring
- 4 existing clinical programs to fruition and expand them
- 5 to support broadened product usage. Do you see that?
- 6 A. Uh-huh.
- 7 Q. And then below that it states invest in
- 8 clinical programs to broaden clinical database into
- 9 nonmalignant chronic pain states. These will be mostly
- 10 IND studies. We envision trials in breakthrough pain
- 11 as more as well -- as well as more general chronic
- 12 pain. Do you see that?
- 13 A. I do.
- MR. MAIER: Objection. Form.
- 0. (By Mr. Faes) And it also states that
- 16 they're going to publish and use that data in the
- 17 short-term for peer-to-peer environments under the WLF.
- 18 Do you see that?
- 19 A. Yes.
- Q. And WLF states for Washington Legal
- 21 Foundation; right?
- A. Uh-huh.
- Q. And you were familiar with the Washington
- Legal Foundation reprints while you were a sales rep

- 1 for Actiq; right?
- 2 A. Yes.
- MR. MAIER: Objection. Form, foundation.
- 4 Q. (By Mr. Faes) And while you were a sales
- 5 rep for Fentora; right?
- A. I don't remember if we had them then.
- 7 Q. Okay. Well, we're going to actually look
- 8 at that a little later, but if the records reflect that
- 9 those WLF reprints continue to be available into 2008,
- 10 that would have been during the time that you were
- 11 promoting or detailing Fentora; right?
- 12 A. Yes.
- 13 Q. And you understood that in general the WLF
- or Washington Legal Foundation reprints were studying
- 15 Actiq for indications other than breakthrough pain in
- 16 patients with cancer; right?
- MR. MAIER: Objection. Form, foundation.
- 18 A. I honestly don't remember.
- 19 Q. (By Mr. Faes) You don't recall if the WLF
- 20 reprints included -- could include studying "Acteeq" --
- 21 sorry -- Actiq -- in indications such as back pain or
- 22 migraines or in noncancer patients?
- MR. MAIER: Objection. Form, foundation.
- A. I don't remember the WLF papers as to

- 1 exactly what they were each, as to know that. I don't
- 2 remember.
- Q. (By Mr. Faes) With regard to envisioning
- 4 trials in breakthrough pain as well as more general
- 5 chronic pain, you did have an understanding, though,
- 6 that that was a company strategy, to study Actiq in
- 7 studies for indications that were beyond the label;
- 8 right?
- 9 A. Yes.
- MR. MAIER: Objection. Form, foundation.
- 11 Q. (By Mr. Faes) And you could make those
- 12 studies available if they were published, for example,
- 13 through the Washington Legal Foundation if the
- 14 physician initiated an off-label discussion; right?
- 15 A. Okay.
- 16 Q. That's true; right?
- 17 MR. MAIER: Objection. Form.
- 18 A. I don't remember, honestly.
- 19 Q. (By Mr. Faes) Well, if a physician came
- 20 to you and said --
- 21 A. I forget how they worked.
- 22 Q. If a physician came to you and said, for
- example, Ms. Kaisen, would Actiq work for migraines?
- 24 Could I use it in one of my patient for migraines?

- 1 Your response would be essentially to say, well,
- 2 Doctor, the Actiq is indicated for breakthrough pain in
- 3 opioid-tolerant patients with cancer only, but I can
- 4 fill out a MIRF or a medical information request form
- 5 for you; right?
- 6 A. Yes.
- 7 MR. MAIER: Objection. Form.
- 8 Q. (By Mr. Faes) And once you filled out
- 9 that form and sent it to the company, the company could
- 10 then send -- could look in their archives and see if
- 11 they had an article that discussed Actiq for the
- indication he was asking for and could send it to him;
- 13 right?
- 14 A. Yes.
- MR. MAIER: Objection. Form, foundation.
- 16 Q. (By Mr. Faes) And that could include
- documents that the company made available through the
- 18 Washington Legal Foundation; right?
- 19 MR. MAIER: Same objection.
- 20 A. I don't know what they sent. They
- answered, but I don't know what they sent exactly. We
- 22 weren't privy to that.
- Q. (By Mr. Faes) But you understood that if
- 24 a article discussing the use of Actiq and the

- 1 indication the doctor was asking about existed, the
- 2 company could send that to the doctor; right?
- 3 A. Yes.
- 4 MR. MAIER: Objection. Foundation.
- 5 Q. (By Mr. Faes) You can set that aside.
- 6 I'm done with it.
- 7 A. What's that?
- 8 Q. You can set that one aside.
- 9 A. Oh.
- MR. BERG: This whole thing.
- 11 Q. (By Mr. Faes) So I'm going to hand you
- what's been marked as Exhibit Number 4 to your
- deposition. 7. I'm going to hand you what's been
- 14 marked as Exhibit Number 7 to your deposition.
- 15 [Exhibit Teva-Kaisen-007]
- marked for identification.
- 17 Q. And this is a document titled business
- 18 plan 2002, Val McGinley. Do you see that?
- A. Uh-huh.
- Q. And that would be you; right?
- 21 A. Yeah.
- Q. That was your name prior to being Kaisen?
- 23 A. Yes.
- Q. And this is a document that you would have

- 1 actually authored; right?
- 2 A. I don't see a trail on it, like an e-mail.
- 3 So if you say so. I don't see an e-mail --
- 4 Q. Well, did you write this document or not?
- 5 A. It looks familiar, but --
- 6 O. Okay. Well, let's look at some of it and
- 7 see if it refreshes any of your memory. Under market
- 8 analysis and overview, you state that the Cleveland
- 9 territory has a steady growth in prescriber counts, TRx
- 10 counts, TRx units, DDD, and TM. Do you see that?
- 11 A. Yes.
- 12 Q. And TRx counts and TRx units means
- 13 prescription counts and prescription units; right?
- 14 A. Yes.
- O. What does DDD and TM mean?
- 16 A. TM would be -- I'm guessing total market.
- 17 I'm not sure what DDD is.
- 18 Q. If you go on it states that --
- 19 A. Total market. I'm not sure. Okay.
- Q. If you go on it states that Cleveland has
- 21 always been very conservative and slow to adapt;
- 22 however, once they become comfortable with a product it
- 23 becomes entrenched. There has never been any coverage
- in my territory prior to my entry and now there is a

- 1 groundwork of established writers. Do you see that?
- 2 A. Yes.
- Q. It says the foundation makes a wonderful
- 4 platform to drive growth and catapult Cleveland into a
- 5 top dollar-generating sales territory for 2002; right?
- 6 A. Yes.
- 7 Q. And the foundation -- that would refer --
- 8 what would that refer to?
- 9 A. Foundation of the established writers, I
- 10 would assume.
- 11 Q. So after reading this, does this refresh
- 12 your recollection at all if this is a document that you
- would have written or if it was just one that would
- 14 have been written by your managers and shared with you?
- MR. MAIER: Objection. Foundation.
- 16 A. If you say it was written by me it was
- 17 written by me. It looks familiar. I'd be more --
- 18 Q. (By Mr. Faes) Well, I mean, I don't want
- 19 to put words in your mouth. What do you --
- 20 A. I would be more comfortable if there was
- 21 an e-mail trail on this.
- Q. Okay. Well, I mean, I'll represent to you
- that it was in your custodial file of documents that
- 24 was received by the company. So assuming that to be

- 1 true, you'd agree with me that you either would have
- 2 written it or would have received and reviewed it;
- 3 right?
- 4 A. Yes.
- 5 MR. MAIER: Objection. Form, foundation.
- 6 O. (By Mr. Faes) If you turn to the second
- 7 page of this document and you list -- you or your
- 8 manager list goaled for 2002.
- 9 A. Okay.
- 10 Q. And it says to have 100 percent of my top
- 11 physicians -- top 15 physicians write Actiq; right?
- 12 A. Yes.
- Q. So that's written in the first person, so
- 14 it's likely that this was probably written by you and
- 15 not by your manager; right?
- MR. MAIER: Objection. Form.
- 17 A. Yes.
- 18 Q. (By Mr. Faes) And if you look down under
- 19 MEPs, entertainment. And MEPs refers to medical
- 20 education programs; right?
- 21 A. Yes.
- Q. And it looks like you've got a list of
- 23 MEPs or medical education programs that you completed
- 24 in 2002; right?

- 1 A. Yes.
- 2 Q. And one of them you list was completed on
- 3 January 24th, 2002.
- 4 A. Okay.
- 5 Q. And it looks like the audience for that
- 6 one was psychiatrists and pain physicians. Do you see
- 7 that?
- 8 A. Yeah.
- 9 Q. So does this indicate that there would
- 10 have been a --
- 11 MR. BERG: It's physiatrists.
- 12 A. It's physiatrists.
- Q. (By Mr. Faes) Physiatrists.
- 14 MR. BERG: Physiatrists, not
- 15 psychologists.
- 16 Q. (By Mr. Faes) Sorry. Let me restate
- 17 that.
- 18 A. Thanks for the pickup. I didn't get that.
- 19 Q. Physiatrist.
- 20 A. It's physiatrists. "Potayto," "potahto."
- Q. And if you turn to the following page of
- 22 this, it reflects that you completed another MEP or
- 23 medical education program on April 18th and the
- 24 audience was high-decile pain management physicians and

- 1 physiatrists in the Toledo area; right?
- 2 A. Number 1 was not in the Toledo area.
- Q. I'm sorry. I've turned the page to Page
- 4 3.
- 5 A. I'm sorry.
- 6 Q. So on the following page of this document
- 7 it also indicates that you completed another medical
- 8 education program on April 18th and the audience was
- 9 high-decile pain management physicians and physiatrists
- in the Toledo area. Do you see that?
- 11 A. Yes.
- 12 Q. And high-decile pain management
- 13 physicians -- what did that mean?
- 14 A. The company would give us what they felt
- were high decile and whatever the decile parameters
- were at the time. I don't remember, but usually they
- 17 were -- I don't remember what the parameters were, but
- 18 high deciles were the ones we needed to target.
- 19 Q. And one of the things that would indicate
- 20 a high-decile physician at that time would have been
- 21 whether they were a high prescriber of other opioids;
- 22 right?
- MR. MAIER: Objection. Form, foundation.
- 24 A. Yes.

- 1 Q. (By Mr. Faes) And that's because you
- 2 would want to target or detail for Actiq someone who
- 3 was already opioid tolerant; right?
- 4 A. Right.
- 5 Q. And so a high-decile pain management
- 6 physician is someone that you would want to
- 7 specifically target or invite to these medical
- 8 education programs; right?
- 9 MR. MAIER: Objection. Form, foundation.
- 10 A. If they treated cancer pain.
- 11 Q. (By Mr. Faes) And if you look down, it
- 12 looks like you had two different events where Dr. James
- 13 Bressi was the speaker, right, for a medical education
- 14 program?
- 15 A. Yes.
- 16 Q. So you would have used Dr. Bressi on
- 17 multiple occasions as a speaker for Actiq; right?
- 18 A. Three as of this page.
- 19 Q. And what do you remember about Dr. Bressi
- 20 and his practice?
- 21 A. Specify the question, please.
- Q. Tell me what you remember about Dr.
- 23 Bressi's practice?
- A. Time frame?

- Q. Well, we're in 2002, so tell me about what
- you remember about Dr. Bressi's practice in 2002 when
- 3 you were using him as a speaker in various programs for
- 4 Actiq.
- 5 A. He was a thought leader in the area, and
- 6 he was a high prescriber due to decile, and oncologists
- 7 would refer to him.
- 8 Q. And how did you select Dr. Bressi as a
- 9 speaker for Actiq?
- 10 MR. MAIER: Objection. Form.
- 11 A. I don't remember. There was different
- 12 criteria every year.
- Q. (By Mr. Faes) So at this time in early --
- in 2002, the selection process for speakers would have
- been more informal; right? There wouldn't have been an
- 16 approved list by the company at this time?
- MR. MAIER: Objection. Form, foundation.
- 18 A. I don't remember.
- 19 Q. (By Mr. Faes) Well, tell me about the
- 20 process you would have used in 2002 in deciding whether
- 21 or not to use a particular physician as a speaker for a
- 22 medical education program.
- MR. MAIER: Objection. Form, foundation.
- A. I don't remember.

- 1 Q. (By Mr. Faes) If you can turn to the
- 2 following page of this document. Oh, sorry. I have
- one more question about Dr. Bressi. What kind of
- 4 doctor did you say Dr. Bressi was?
- 5 A. Pain management. Anesthesia.
- 6 O. Didn't he also practice in physical
- 7 rehabilitation?
- MR. MAIER: Objection. Form, foundation.
- 9 A. I don't know.
- 10 Q. (By Mr. Faes) So in several of these
- 11 events, the target audience is a physiatrist; right?
- 12 Is included in the target audience for the medical
- 13 education program?
- 14 A. There were several different specialties.
- Q. And physiatrist was one of them; right?
- 16 A. Yes. If they treated cancer pain.
- 17 Q. But a physiatrist is a different specialty
- than a oncologist or a pain specialist; right?
- 19 A. Yes.
- 20 O. And at this time -- and was it true that
- 21 your superiors or your bosses at the company would have
- 22 known that physiatrists were being invited to and
- 23 attending these medical education programs for Actiq?
- MR. MAIER: Objection. Foundation.

- 1 A. Yes.
- Q. (By Mr. Faes) And did anyone at the
- 3 company ever express any concerns or tell you that you
- 4 shouldn't do that, that you should only invite
- 5 oncologists and pain specialists to medical education
- 6 programs?
- 7 MR. MAIER: Objection. Form.
- A. I don't remember.
- 9 Q. (By Mr. Faes) So you'd agree with me that
- 10 nobody -- none of your superiors, none of your bosses
- 11 at the company ever told you that you shouldn't invite,
- 12 for example, a physiatrist to a medical education
- 13 program for Actiq because that was inconsistent with
- 14 the risk map for the Actiq?
- MR. MAIER: Objection. Form.
- 16 A. Can I answer the --
- MR. BERG: Yeah.
- 18 A. If they treated -- and I said this before.
- 19 If they treated breakthrough cancer pain, they were
- 20 invited. So there were "physiahtrists" or
- 21 "physyatrists" that did treat cancer pain.
- 22 Q. Sure, I understand that. My question is
- 23 simply, your superiors at the company were aware that
- 24 physiatrists were attending these medical education

- 1 programs; right?
- 2 MR. MAIER: Objection. Form, foundation.
- A. I don't know what they looked at, so I
- 4 quess they did.
- 5 Q. (By Mr. Faes) Well, you'd agree with me
- 6 that nobody at the -- none of your superiors at the
- 7 company ever came to you and said, hey, you shouldn't
- 8 be inviting or allowing, for example, physiatrists to
- 9 attend MEPs because that's inconsistent with the risk
- 10 map? Nobody ever told you that; right?
- 11 A. No.
- MR. MAIER: Objection. Form.
- Q. And if someone had told you that,
- 14 somebody -- a superior, your boss at the company -- you
- would have done what you were told; right?
- 16 A. Yes.
- 17 Q. (By Mr. Faes) If you turn to the
- 18 following page of this document under regional
- 19 symposium, it states MediCom Worldwide and myself --
- 20 I'll slow down.
- 21 A. What page are we on?
- Q. I'll start over.
- A. Thank you.
- Q. Sorry. I'm trying to get you out of here

- 1 as fast as I can, so --
- 2 A. I appreciate that.
- 3 Q. So we're under regional symposium.
- 4 A. Got it.
- 5 Q. And it states that MediCom Worldwide and
- 6 myself instrumented a regional symposium in Cleveland
- on May 22nd, 2002. There were 38 key physicians from
- 8 Cleveland, Akron, Warren, Canton, and Youngstown areas.
- 9 Dr. "Guiden"?
- 10 A. "Goodin."
- 11 Q. Am I pronouncing that right?
- 12 A. "Goodin."
- Q. Gudin was the guest speaker. He did a
- 14 terrific job. I am already seeing a great ROI. Do you
- 15 see that?
- 16 A. Yes.
- 17 Q. And these would have been your comments at
- 18 the time that Dr. Jeffrey -- I'll probably pronounce it
- 19 wrong again --
- 20 A. "Goodin."
- 21 Q. -- Gudin was a guest speaker and you were
- 22 seeing a terrific ROI or return on investment from that
- 23 speaking program; right?
- MR. MAIER: Objection. Form.

- 1 A. Yes.
- Q. (By Mr. Faes) And return on investment or
- 3 ROI was an important factor in utilizing these medical
- 4 education programs; right?
- 5 MR. MAIER: Objection. Form.
- 6 A. Educating.
- 7 Q. (By Mr. Faes) Right. The purpose of
- 8 these programs was to educate other doctors on Actiq;
- 9 right?
- 10 A. Yeah.
- 11 Q. And the hope was that once these other
- doctors were educated that they would hopefully start
- 13 prescribing Actiq or trying it in their patients as
- 14 well; right?
- 15 A. Yes.
- MR. MAIER: Objection. Form.
- Q. (By Mr. Faes) And with those additional
- 18 prescriptions would be more revenue for the company;
- 19 right?
- 20 A. Yes.
- Q. And that's what that refers to, is return
- on investment, because these speaking programs had a
- 23 cost; right?
- MR. MAIER: Objection. Form, foundation.

- 1 A. I don't remember, but yes, I guess they
- 2 would.
- Q. (By Mr. Faes) Well, I mean, certainly you
- 4 knew that like Dr. Gudin, for example, or Dr. Bressi --
- 5 A. But the MediCom Worldwide -- I don't
- 6 remember them, so --
- 7 Q. Well, in general, doctors like Dr. Bressi,
- 8 who gave three different talks according to this
- 9 document, the company, Cephalon, would pay them for
- 10 their time --
- 11 A. Uh-huh.
- 12 Q. -- to come to these symposiums and speak;
- 13 right?
- 14 A. Yes.
- Q. And there was a cost for that?
- 16 A. Yes.
- 17 Q. And you would want to look at whether or
- 18 not you were seeing a return on investment down the
- 19 line if the people -- those doctors that you hired to
- 20 talk -- that those doctors that they talked to were
- 21 actually writing prescriptions or trying Actiq after
- the medical education program was done; right?
- MR. MAIER: Objection. Form.
- 24 A. Yes.

- 1 Q. (By Mr. Faes) And that's what the ROI or
- 2 return on investment refers to; right?
- MR. MAIER: Objection. Form, foundation.
- 4 A. Not necessarily.
- 5 Q. (By Mr. Faes) But that's one of the
- 6 aspects; right?
- 7 MR. MAIER: Objection. Form.
- 8 A. Education, return on investment.
- 9 Educating was important.
- 10 Q. (By Mr. Faes) Right. So if you look on
- 11 the following page of this document, you've got a list
- of your top physician targets for 2002; right?
- 13 A. I don't see where you're saying.
- MR. BERG: Where is this?
- Q. (By Mr. Faes) It's the following page.
- 16 A. I see barriers to success.
- 17 Q. Maybe it's two pages forward. It's -- the
- 18 Bates ending is in 7915.
- 19 A. Okay.
- Q. If you look at the bottom.
- 21 A. Got it now.
- Q. Okay. So we're on the page with Bates
- 23 ending 7195 and you see you've got top physician
- 24 targets listed for 2002; right?

- 1 A. Yes.
- Q. And excuse me. Your top target is Dr.
- 3 James Bressi; right?
- 4 A. Yes.
- 5 Q. And you can see -- and that's the same
- 6 doctor that you were already using as a speaker; right?
- 7 A. Yes.
- Q. And you can see he was writing at this
- 9 time 39 prescriptions for Actiq a month; right?
- 10 A. 39 in three months.
- 11 Q. Oh, 39 in three months. Thanks for that
- 12 correction. And his specialty was anesthesiology;
- 13 right?
- 14 A. Anesthesiology, pain management.
- Q. And Greg Thomas was your second largest
- 16 target, and he was a physiatrist; right?
- 17 A. (Nodding "yes.")
- 18 Q. And your third target was -- third biggest
- 19 target was Mark Allen, who was an anesthesiologist;
- 20 right?
- 21 A. Uh-huh. Pain management.
- 22 Q. And the four -- your fourth biggest target
- was -- his specialty was family practice?
- MR. MAIER: Objection. Form.

- 1 A. (Nodding "yes.")
- Q. (By Mr. Faes) And your fifth largest
- 3 target was doc -- I assume Dr. Heather Scullin, and her
- 4 specialty is PM and R. Do you see that?
- 5 A. Uh-huh.
- 6 O. And PM and R would stand for physical
- 7 medicine and rehabilitation; right?
- 8 A. Uh-huh.
- 9 Q. So at this time in 2002, your -- none of
- 10 your top five targets were oncologists or pain
- 11 management specialists; right?
- MR. BERG: Well, objection. I think she
- 13 said one of the anesthesiologists was a pain
- 14 management.
- 0. (By Mr. Faes) Okay. So which of the
- 16 anesthesiologists -- which of the people on this list
- 17 did you consider a pain management specialist?
- 18 A. James Bressi.
- 19 Q. Okay.
- 20 A. Let me finish. Mark Allen.
- 21 Q. Okay.
- 22 A. I can't remember, but I think Greg Thomas
- too was pain management certified.
- Q. So at this time in 2002, it would be true

- 1 that two of your top five targets were not pain
- 2 management specialists or oncologists; right?
- MR. MAIER: Objection. Form.
- 4 A. Heather Scullin was pain management too,
- 5 from what I remember.
- 6 Q. (By Mr. Faes) But at least according to
- 7 this document, which is in your business plan dated
- 8 2002, it lists her specialty as PM and R, which is
- 9 physical --
- 10 A. Medicine and rehab.
- 11 Q. -- medicine and rehabilitation; right?
- 12 A. Uh-huh.
- Q. Would you have called on physical medicine
- 14 and rehabilitation doctors in 2002 for Actiq?
- 15 A. I called on whoever they wanted me to call
- on according to the decile.
- Q. And when you say whoever they wanted you
- 18 to call on --
- 19 A. The company.
- 20 Q. -- you mean the company, your superiors;
- 21 right?
- A. (Nodding "yes.")
- MR. MAIER: Objection. Form.
- Q. (By Mr. Faes) And nobody at this time in

- 1 2002 ever told you that someone with a primary
- 2 specialty of physical medicine and rehabilitation would
- 3 be an inappropriate person to call on because they
- 4 weren't a pain management specialist or oncologist;
- 5 right? Nobody ever told you that?
- 6 A. No.
- 7 MR. MAIER: Objection. Form.
- 8 Q. (By Mr. Faes) And if somebody had told
- 9 you that, that that was -- you shouldn't call on that
- 10 type of doctor because it's inconsistent with the risk
- 11 map, you would have done what you were told; right?
- 12 A. Yes.
- Q. Are you done? I don't want to cut you
- 14 off.
- 15 A. That's fine.
- 16 Q. Okay. And at this time it indicates that
- 17 you were also calling on family practitioners like Dr.
- 18 Edward Urban; right?
- 19 A. Yes.
- Q. And nobody at the company or your
- 21 higher-ups, your superiors, your bosses -- nobody ever
- 22 told you that it would be inappropriate to call on a
- 23 family practice person for Actiq; right?
- MR. MAIER: Objection. Form.

- 1 A. No.
- Q. (By Mr. Faes) And you would have shared
- 3 this plan with your manager; right? Your manager would
- 4 have known that this was your plan and this is your top
- 5 five targets for 2002; right?
- 6 A. Yes.
- 7 Q. And if your boss had a problem with any of
- 8 this, he would have told you and you would have done as
- 9 you were instructed; right?
- 10 MR. MAIER: Objection. Foundation.
- 11 A. Yes.
- Q. (By Mr. Faes) And nobody at the company
- ever told you that Ms. Kaisen, which I think was
- 14 McGinley at the time -- nobody ever told you, Ms.
- 15 Kaisen, you shouldn't be calling on family practice
- 16 specialty doctors because that's inconsistent with the
- 17 risk map that says you're only supposed to call on
- 18 oncologists and pain specialists; right?
- MR. MAIER: Objection. Form.
- 20 A. I don't remember.
- Q. (By Mr. Faes) Well, if someone had, it's
- 22 probably something you would have remembered because
- 23 you would have changed your plan and not called on them
- 24 anymore; right?

- 1 MR. MAIER: Objection. Form, foundation.
- 2 A. Yes.
- Q. (By Mr. Faes) And if somebody had told
- 4 you that, you would have done as you were instructed by
- 5 your superiors; right?
- 6 A. Yes. Yes.
- 7 Q. Then if you look down you've got a Dr.
- 8 Brocker in your six through 15 targets listed as one of
- 9 your targets as well, and he's -- his specialty is
- 10 neurologist; right?
- 11 A. Pain management too.
- 12 Q. But did you -- but listed here in your
- document, in your business plan, you don't list him as
- 14 a pain management specialist; you list his specialty as
- 15 neurology; right?
- 16 A. Because the box is only so big. That's
- 17 me. Sorry.
- 18 Q. Okay. Well, let me ask you this.
- 19 A. That's being honest.
- Q. Okay. That's fine. Fair enough. I don't
- 21 want to put words on your mouth. I apprec --
- 22 A. My typing skills are not that great.
- Q. No, I appreciate you offering that.
- 24 That's why we do these depositions, is because

- 1 sometimes what's reflected on the document is different
- than what a person remembers, so that's why we go
- 3 through it. But let me ask you this. Would you have
- 4 called on somebody with a primary specialty of
- 5 neurology at this time if the company had asked you to?
- 6 MR. MAIER: Objection. Form.
- 7 A. If the company asked me to?
- 8 Q. (By Mr. Faes) Yes. Did you -- well, let
- 9 me ask it another way.
- 10 A. Rephrase that.
- 11 Q. Let me -- yeah. Let me ask it another
- 12 way. Did you call on people with a primary specialty
- of neurologist when you were promoting or detailing
- 14 Actiq -- Actiq?
- 15 A. Neurology pain management, yes.
- 16 Q. Right. And so no one --
- 17 A. No.
- 18 Q. No one at Cephalon ever told you that it
- 19 was inappropriate for you to call on that type of
- 20 doctor; right?
- 21 A. No.
- MR. MAIER: Objection. Form.
- Q. (By Mr. Faes) And nobody ever told you
- that that was inconsistent with the risk map that said

- 1 you were only supposed to call on patients who are --
- 2 strike that. No one ever told you that that was
- inappropriate, to call on somebody with a primary
- 4 specialty of neurology, because that was inconsistent
- 5 with the risk map that said the company would only call
- 6 on doctors with a specialty in oncology or pain
- 7 management; right?
- MR. MAIER: Objection. Form.
- 9 A. Hang on. I'm reading this, and I'm not
- 10 sure I said that. I didn't answer exactly, I don't
- 11 think.
- MR. BERG: Did anyone in the company tell
- 13 you that any of the people you were calling on was
- 14 wrong?
- 15 A. No.
- 16 Q. (By Mr. Faes) And that included
- 17 neurologists; right?
- 18 A. I quess.
- 19 Q. If someone at the company --
- 20 A. If someone told me, yes, then I would.
- Q. Let me get the whole question out.
- A. Yeah.
- Q. If someone at the company had ever told
- 24 you that it was inappropriate to call on a neurologist

- 1 to sell or promote Actiq, you would have listened to
- 2 that direction and followed that direction from the
- 3 company; right?
- 4 A. Yes. All right.
- 5 Q. Okay. Just looking down here on personal
- 6 development.
- 7 A. Uh-huh.
- 8 Q. Says please advise, coach me of a
- 9 development plan or pathway to become a district
- 10 manager with Cephalon. I can bring 18 years of
- 11 hospital pharmaceutical sales experience to the table.
- 12 13 of those years were in pain management and oncology.
- 13 I have also had almost a full year experience as an
- 14 interim district manager; right?
- 15 A. Yes.
- 16 Q. And this was a request that you put in to
- 17 your superiors at Cephalon at the time; right?
- 18 A. (Nodding "yes.")
- 19 Q. Who was your district manager at this
- 20 time?
- 21 A. I don't remember.
- Q. When it says you had a full year of
- 23 experience as an interim district manager, was that at
- 24 Cephalon, or was that somewhere else?

- 1 A. Astra. 1996 or 1995 or 1994.
- 2 Q. Do you remember if anyone at Cephalon ever
- 3 acted on this request?
- 4 MR. MAIER: Objection. Foundation.
- 5 A. I don't remember.
- 6 O. (By Mr. Faes) You can set that document
- 7 aside. I'm going to hand you what's been marked as --
- 8 doing okay?
- 9 A. Yeah. Thank you.
- 10 Q. I'm going to hand you what's been marked
- 11 as Exhibit Number 8 to your deposition.
- 12 [Exhibit Teva-Kaisen-008
- marked for identification.]
- 14 Q. You want to keep the one with the sticker.
- 15 You get all the ones with the stickers because you're
- 16 the quest of honor.
- 17 A. Okay.
- 18 Q. So this is a document titled 2003 Actiq
- 19 marketing plan. Do you see that?
- A. Uh-huh.
- 21 Q. This is the type of document that we were
- 22 talking about earlier? This is a document put together
- 23 by the marketing department that would have been shared
- 24 with the field sale specialists such as yourself;

- 1 right?
- 2 A. Yes.
- 3 Q. And the marketing department and the
- 4 company would have relied as you as the field
- 5 specialist, as kind of the person in the trenches, to
- 6 carry out at least some of the strategies that are laid
- 7 out in this plan; right?
- 8 A. Yes.
- 9 Q. So if you can turn to Page 2 of this
- 10 document. Under executive summary it states 2002
- 11 performance review. Cephalon experienced another
- 12 extraordinarily successful year with Actiq in 2002.
- 13 This achievement can be attributed primarily to focused
- 14 and integrated marketing and sales efforts, which build
- upon the successful repositioning of Actig in 2001. Do
- 16 you see that?
- 17 A. Yes.
- 18 Q. Is that consistent with your memory that
- 19 the company had a extraordinarily successful year with
- 20 Actiq in 2002?
- 21 MR. MAIER: Objection. Foundation.
- 22 A. I don't remember, but okay.
- Q. (By Mr. Faes) But do you have any reason
- 24 to dispute --

- 1 A. No.
- 2 O. -- this document that states that the
- 3 company did have an extraordinarily successful year
- 4 with Actiq?
- 5 A. I don't dispute it.
- 6 Q. I can have you turn to Page 4 of this
- 7 document. And the top of this is labeled situation
- 8 analysis, 2002 review. Do you see that?
- 9 A. Yes.
- 10 Q. And it says 2002 promotional strategy by
- 11 key marketing issue. Do you see that?
- 12 A. Hang on. Thank you.
- Q. So helpful to have the guy pulling
- 14 everything out for you, isn't it?
- 15 A. Whew. It's very helpful. Okay. Repeat
- 16 your question.
- Q. So this -- so I'm just saying -- I'm just
- 18 trying to orient you on the document.
- 19 A. Okay.
- Q. You see that we're looking at a document
- 21 under 2002 promotional strategy by key marketing issue;
- 22 right?
- 23 A. Yes.
- Q. And this appears to be a recap of

- 1 promotional strategies that were used in 2002; right?
- 2 A. Yeah.
- Q. And as we saw earlier, the -- 2002 was a
- 4 very successful year for Actiq and the company; right?
- 5 A. Okay.
- 6 Q. And if you look on the second issue, it
- 7 says one of the issues was lack of knowledge in the
- 8 assessment and treatment of breakthrough pain, BTP,
- 9 among targeted physician specialties, and the strategy
- 10 to deal with that issue is to educate targeted
- 11 physician specialties about the benefits of assessing
- 12 and treating breakthrough pain, BTP, with Actiq. Do
- 13 you see that?
- 14 A. I do.
- 15 Q. Is it your -- strike that. Is that one of
- 16 the strategies that you used as a sales representative
- 17 in 2002?
- 18 A. I don't remember.
- 19 Q. If you look down at the last issue and
- 20 strategy, do you see that the last issue listed is
- 21 limited direct promotional reach, and the strategy is
- 22 direct the most effective promotional and educational
- 23 efforts to the highest potential targeted physicians,
- 24 maximize ROI or return on investment of promotional and

- 1 educational efforts? Do you see that?
- 2 A. Yes.
- Q. And that's consistent with what we talked
- 4 about earlier, that you want to maximize the return on
- 5 investment of educational efforts such as the speaker
- 6 programs that we talked about earlier; right?
- 7 MR. MAIER: Objection. Form.
- 8 A. Yes.
- 9 Q. (By Mr. Faes) And that was something that
- 10 you were trained and was communicated by the marketing
- department, was a strategy that should be employed in
- 12 successfully detailing Actiq; right?
- 13 A. Could you rephrase that?
- 14 Q. I'll try.
- 15 A. Well --
- 16 MR. BERG: You're referring to the
- 17 strategy at the bottom of the page?
- 18 Q. (By Mr. Faes) Let me reask the question.
- 19 A. Thank you.
- Q. Would you agree with me that the strategy
- of directing the most effective promotional and
- 22 educational efforts to the highest potential targeted
- 23 physicians, maximizing ROI of promotional and
- 24 educational efforts, was a strategy that was

- 1 communicated to you that should be employed when
- 2 detailing or promoting Actiq? Essentially that was
- 3 something you were told you should do; right?
- 4 MR. MAIER: Objection. Form.
- 5 A. I don't remember.
- 6 Q. (By Mr. Faes) But you -- I mean, this is
- 7 a -- strike that. As we talked about earlier, the
- 8 marketing plan came out every year and it would have
- 9 been shared with representatives in the field such as
- 10 yourself?
- 11 A. Uh-huh.
- 12 Q. And if the company directed you to employ
- 13 a particular strategy or tactic, you would generally
- 14 follow the instructions you were given; right?
- 15 A. Yes.
- Q. And this is one of the strategies or
- 17 directions they gave you; right?
- 18 A. Yes.
- 19 Q. If you can turn to Page 14 of this
- 20 document. We're going to start down at the bottom in
- 21 the section stated tracking studies. Actually, let's
- 22 start above that, because this is in a section titled
- usage by disease area. Do you see that?
- 24 A. Yes.

- 1 Q. So it says in this document that the
- 2 current data utilized by Cephalon for disease usage
- 3 information is captured by the physician drug and
- 4 diagnosis audit, PDDA, from Scott Levin. Do you see
- 5 that?
- 6 A. I do.
- 7 Q. Is that accurate that at this time the
- 8 company would have been using and tracking disease
- 9 usage information captured by this Scott Levin?
- MR. MAIER: Objection. Form, foundation.
- 11 A. I don't remember.
- 12 Q. (By Mr. Faes) Well, if you look down
- 13 under tracking studies, it states that in May and
- 14 December of 2001, primary research was implemented to
- 15 educate product awareness, perception, and use by pain
- 16 type among pain specialists and oncologists. Obviously
- oncologists included in both tracking studies cited use
- of Actiq primarily in the treatment of breakthrough
- 19 cancer pain. Additionally, participating pain
- 20 specialists cited Actiq usage in the follow disease
- 21 states, illustrating a wide spectrum of application and
- 22 opportunity. Do you see that?
- 23 A. Yes.
- Q. And if you turn to the following pain --

- 1 or strike that. If you would turn to the following
- 2 page, you see a table that it's referring to, and it
- 3 states usage of Actiq cited by pain specialists. Do
- 4 you see that?
- 5 A. I see it.
- 6 Q. And according to this, it looks like the
- 7 company received information that stated that 48
- 8 percent of MDs have written prescriptions for lower
- 9 back pain; right?
- MR. MAIER: Objection. Form, foundation.
- 11 A. I see.
- 12 Q. (By Mr. Faes) 20 percent of doctors have
- 13 written Actiq for osteoarthritis.
- MR. MAIER: Same objection.
- Q. (By Mr. Faes) 24 percent for post-trauma.
- MR. MAIER: Same objection.
- 17 Q. (By Mr. Faes) 16 percent for diabetic
- 18 neuropathy.
- MR. MAIER: Same objection.
- Q. (By Mr. Faes) 12 percent for rheumatoid
- 21 arthritis and 24 percent for other type of headache.
- 22 Do you see that?
- 23 A. I do.
- MR. MAIER: Same objection.

- 1 Q. (By Mr. Faes) You would agree with me
- 2 that all of these uses for Actiq would be off-label;
- 3 right?
- 4 MR. MAIER: Objection. Form.
- 5 A. It says cancer patients.
- 6 MR. BERG: The ones highlighted.
- 7 A. Oh, the one --
- 8 Q. (By Mr. Faes) I'm sorry?
- 9 A. It says cancer patients, what I'm reading.
- 10 Q. Well, that's the second line, right -- 40
- 11 percent are cancer patients?
- 12 A. Oh, you're talking highlighted? I'm
- 13 looking at this versus this. You want highlighted or
- 14 not?
- Q. Well, I think we're both looking at the
- 16 same thing. I'm just talking about different parts of
- 17 it.
- 18 A. Okay. Show me which part you're loo --
- 19 MR. BERG: The highlighted.
- 20 A. The highlighted?
- Q. (By Mr. Faes) Yes.
- 22 A. Oh, sorry. Yes.
- Q. So you would agree with me that all of
- 24 these uses -- lower back pain, osteoarthritis,

- 1 post-trauma, diabetic neuropathy, rheumatoid arthritis,
- 2 and other type of headache -- would all be off-label
- 3 uses of Actiq?
- 4 A. Yes.
- 5 MR. MAIER: Objection. Form, foundation.
- 6 O. (By Mr. Faes) And this would be data that
- 7 the company is aware of, that at this time in 2003 some
- 8 doctors -- in fact, a high percentage of doctors in
- 9 some categories -- were using Actiq off-label; right?
- MR. MAIER: Objection. Form.
- 11 A. If that's what it says.
- 12 Q. (By Mr. Faes) And this is information
- that would have been communicated to you as a sales
- 14 representative who needed to know this information so
- they could use it out in the field; right?
- MR. MAIER: Objection. Form.
- 17 A. I don't remember.
- 18 Q. (By Mr. Faes) Well --
- 19 A. I don't remember this in particularly.
- Q. Okay. So did the company -- is it true
- 21 then that the company never told you any of this, that
- 22 all of these subspecialties were writing Actiq
- off-label in 2003?
- MR. MAIER: Objection. Form.

- 1 A. I don't remember.
- Q. (By Mr. Faes) Is this information you
- 3 would have wanted to know as a sales specialist for
- 4 Actiq in 2003?
- 5 A. No, because my indication was for
- 6 breakthrough cancer pain, period.
- 7 Q. So if physicians in your territory were
- 8 using Actiq off-label, would you want to know that?
- 9 MR. MAIER: Objection. Form.
- 10 A. I don't know how to answer the question.
- MR. BERG: Just --
- 12 A. I don't remember.
- 13 Q. (By Mr. Faes) So you don't remember if
- 14 you would have wanted to know in 2003 whether
- 15 physicians you were detailing for Actiq were using the
- 16 product off-label?
- 17 MR. MAIER: Objection. Form.
- 18 A. I don't remember. Help me out here.
- MR. BERG: What was that?
- 20 A. He's fishing and -- I don't remember this.
- 21 Q. (By Mr. Faes) So if you --
- 22 MR. BERG: I understand that -- you just
- 23 want to repeat the question in terms of --
- MR. FAES: Right. So my --

- 1 MR. BERG: Irrespective of the table,
- 2 you're asking if she had come to know --
- A. Would I have wanted to? I don't remember
- 4 at that time what I would have wanted.
- 5 Q. (By Mr. Faes) Fair enough.
- 6 A. That's 19 years ago, or 17 years ago.
- 7 Q. That's fair enough. Let's move on. I'm
- 8 going to go to the following pages -- page of this
- 9 document, and we're under the section labeled clinical
- 10 needs to expand usage. Do you see that?
- 11 A. Yes.
- 12 Q. And it states that as noted in the Actiq
- 13 2002 marketing plan, anesthesiologists and other pain
- 14 specialists who have similar prescribing habits may not
- 15 require substantial evidence to implement Actiq in
- 16 numerous disease states other than breakthrough cancer
- 17 pain due to the reasons listed above, primarily --
- 18 particularly their familiarity with fentanyl. Do you
- 19 see that?
- 20 A. I do.
- 21 MR. MAIER: Objection. Form. Misstates
- 22 the document.
- Q. (By Mr. Faes) And if you look above it
- 24 talks about what those factors are. Actiq used by pain

- 1 specialists in the aforementioned disease states may be
- 2 due to several reasons --
- 3 A. Thank you.
- 4 Q. -- including familiarity with fentanyl,
- 5 comfort with fentanyl, comfort with using --
- 6 A. Can you slow down, please?
- 7 O. Sure.
- 8 A. Because I'm trying to flip with him.
- 9 Q. No. Yeah, I understand. I can slow down.
- 10 A. Thank you. I'm just -- need to have
- 11 direct questions to me, please, with the information in
- 12 front of me, period. Thank you.
- 13 Q. Understood. So if you look at the section
- 14 above.
- 15 A. Okay.
- 16 O. It talks about what those reasons are that
- 17 some physicians may not require substantial clinical
- 18 evidence to implement Actiq in numerous disease states
- other than breakthrough cancer pain.
- 20 A. I don't remember this.
- Q. Okay. So nobody at the company ever
- 22 communicated to you that there were numerous physicians
- that were willing to use Actig for disease states other
- than breakthrough cancer pain with limited clinical

- 1 evidence?
- MR. MAIER: Objection. Form, foundation.
- 3 A. Restate that question, please.
- 4 Q. (By Mr. Faes) Sure. Did anyone from
- 5 Cephalon at this time communicate to you that there
- 6 were a number of physicians that would be comfortable
- 7 using Actiq in numerous disease states other than
- 8 breakthrough cancer pain with limited evidence?
- 9 MR. MAIER: Same objection.
- 10 A. I don't remember.
- 11 Q. (By Mr. Faes) If that had been
- 12 communicated to you, is that information that you would
- 13 have used in the field?
- MR. MAIER: Objection. Form.
- 15 A. If it did not have breakthrough cancer
- 16 pain I would have not used it in the field, period.
- 17 Q. (By Mr. Faes) So if we look down in this
- 18 strategy planning document, starting with the disease
- 19 states. It's about three lines down from where we are.
- 20 So in this strategic marketing plan it states that the
- 21 disease states that represent the largest growth
- 22 opportunities for Actiq include but are not limited to
- osteoarthritis, rheumatoid arthritis, chronic back
- 24 pain, migraine headaches, complex regional pain

- 1 syndrome, and postherpetic neuralgia. Do you see that?
- 2 A. I do.
- MR. MAIER: Objection. Form.
- 4 Q. (By Mr. Faes) Is this information that --
- 5 well, first of all, these are all -- these disease
- 6 states in this 2003 strategic marketing plan which was
- 7 distributed to sales reps such as yourself --
- 8 A. Uh-huh.
- 9 Q. -- states that these disease states
- 10 represent the largest growth opportunities; right?
- 11 A. Okay.
- 12 Q. And all -- you would agree with me that
- 13 all of these disease states would represent off-label
- 14 uses of Actiq; right?
- MR. MAIER: Objection. Form.
- 16 A. Yeah.
- 17 Q. (By Mr. Faes) Did anyone at Cephalon ever
- 18 tell you to promote Actiq for these disease states?
- 19 A. Not that I remember.
- Q. Would you agree that if anyone at Cephalon
- 21 ever did tell you to promote Actiq for these disease
- 22 states, that would be inappropriate?
- 23 A. Yes.
- Q. You'd agree that that would be off-label?

- 1 A. Yes.
- 2 Q. You'd agree that that -- because it's
- 3 off-label that would be illegal?
- 4 MR. MAIER: Objection. Form.
- 5 A. Yes.
- 6 O. (By Mr. Faes) Do you have any idea why
- 7 then it would be included in this company 2003
- 8 marketing plan identifying these as the largest growth
- 9 opportunities for Actiq?
- MR. MAIER: Objection. Form, foundation.
- 11 A. I don't remember this, period. I can't
- 12 surmise and guess what they were thinking.
- Q. (By Mr. Faes) Well, you'd agree with me
- 14 that this -- if this was one of the company's marketing
- 15 strategies that this is an inappropriate marketing
- 16 strategy to promote Actiq to patients in these type of
- 17 patient populations; right?
- MR. MAIER: Objection. Form, foundation.
- 19 A. I just don't know where you're going with
- 20 this. I don't remember this document, period.
- 21 Q. (By Mr. Faes) I understand. But my
- 22 question is, you'd agree with me that if it was the
- 23 company's strategy to promote Actiq to patients in
- these patient populations, that would be inappropriate;

- 1 right?
- 2 A. Yes.
- MR. MAIER: Objection. Form, foundation.
- 4 Q. (By Mr. Faes) And we can agree that this
- 5 is information --
- A. I just can't remember what complex
- 7 regional pain syndrome is.
- 8 Q. We can agree that this is information
- 9 that's included in the 2003 --
- 10 A. Yes.
- 11 Q. -- Actiq marketing plan; right?
- MR. BERG: One moment.
- 13 [Discussion off the record.]
- Q. (By Mr. Faes) So if you -- just two more
- things in this document and then we'll be done with it.
- 16 If you can turn to Page 19 of this document. Bates
- 17 numbers ending in 2901, if that helps orient yourself.
- 18 And I want you to look at the pie chart --
- A. Uh-huh.
- 20 Q. -- below in the caption that states Actiq
- 21 marketing designated sales targets by specialty. 8,464
- 22 physicians. Do you see that?
- 23 A. Uh-huh.
- Q. And this would appear to be a breakdown of

- 1 targets that the company -- the specialties that the
- 2 company was targeting for Actiq; right?
- MR. MAIER: Objection. Foundation.
- 4 A. Okay.
- 5 Q. (By Mr. Faes) And it looks like oncology
- 6 is 16 percent and ANES pain, which I assume is
- 7 anesthesiologists and pain specialists --
- 8 A. Yes.
- 9 Q. -- is 24 percent. And all the other
- 10 categories represent over 50 percent of the pie, right,
- 11 combined?
- 12 A. Yes.
- Q. So is this consistent with your
- 14 recollection at this time that less than 50 percent of
- 15 the designated sales targets by specialty were pain
- 16 specialists or oncologists?
- MR. MAIER: Objection. Form.
- 18 A. I don't remember at this time -- that
- 19 time.
- 20 O. (By Mr. Faes) Assuming this to be true,
- 21 that at this time less than 50 percent of the targeted
- 22 physicians for Actiq were pain specialists or
- oncologists, do you remember anyone ever expressing
- 24 concern that targeting physicians in these other

- 1 specialties was inconsistent with the risk map that
- 2 stated that only oncologists and pain specialists were
- 3 supposed to be targeted for Actiq promotion?
- 4 MR. MAIER: Objection. Form.
- 5 A. I don't remember.
- 6 O. (By Mr. Faes) If you had been told that,
- 7 is that something you likely would have remembered?
- MR. MAIER: Objection. Form.
- 9 A. I don't remember.
- 10 Q. (By Mr. Faes) If you had been told that,
- 11 is that -- that it was inappropriate to target anyone
- other than cancer specialists or pain specialists, you
- 13 would have followed that direction by the company;
- 14 right?
- 15 A. Thank you. I would have followed the
- 16 direction, and the direction was always for
- 17 breakthrough cancer pain, period.
- 18 Q. Right. There wasn't any restriction that
- 19 what you recall on the specialty of the doctor that you
- 20 could call on?
- 21 MR. MAIER: Objection. Form.
- 22 A. Certain specialties treated cancer
- 23 patients, period. Certain physicians.
- Q. (By Mr. Faes) So if we can turn to Page

- 1 38 of this document, and this is the last thing we're
- 2 going to do with this one. If you can go down to --
- 3 well, the top part of this document is listing key
- 4 marketing issues, and it says there are seven key
- issues that need to be addressed for Actiq in 2003.
- 6 And if you look at the second to the bottom one, one of
- 7 the seven key issues listed is limited clinical data
- 8 outside of breakthrough cancer pain. Do you see that?
- 9 A. Uh-huh.
- Q. And it says e.g., OA, RA, chronic back
- 11 pain, CPRS, that highlights the need for rapid pain
- 12 relief as well as producing --
- 13 A. Pharmacoeconomic.
- Q. Pharmacoeconomic -- thank you -- benefit
- 15 data will be crucial for -- in growing the use of Actiq
- 16 as well as overcoming current and future reimbursement
- 17 hurdles. Do you see that?
- 18 A. Uh-huh.
- 19 Q. Why would that be a key marketing issue
- that would need to be addressed for Actiq in 2003? Why
- 21 would the company need to develop efficacy data outside
- of breakthrough cancer pain?
- MR. MAIER: Objection. Form, foundation.
- A. I don't remember this, and this is a huge

- 1 document.
- Q. (By Mr. Faes) Well, let me ask you this.
- A. Are you sure it wasn't written by
- 4 marketing? What did we get as sales reps?
- 5 Q. Right. I mean, we talked about the fact
- 6 that you -- that marketing plans would have been shared
- 7 with you.
- 8 A. Disseminated. But this document in
- 9 particular -- was this marketing's personal document,
- or was this handed to the sales reps? Because I don't
- 11 remember.
- 12 Q. Well, in general you remember being -- you
- 13 remember seeing documents with this bell on the front
- 14 of it; right?
- 15 A. Yes.
- 16 Q. So let me get back to my question. Now
- 17 I've lost my page. First of all, were you aware that
- 18 the company believed that developing efficacy data
- 19 outside of breakthrough cancer pain was a key marketing
- issue that needed to be addressed?
- 21 MR. MAIER: Objection. Foundation.
- 22 A. Redo that question, please.
- Q. (By Mr. Faes) Were you aware --
- A. Because there's three different questions

- 1 in there.
- 2 Q. So were you aware that the company
- 3 believed that developing efficacy data outside of
- 4 breakthrough cancer pain was a key marketing issue that
- 5 needed to be addressed in 2003?
- 6 MR. MAIER: Objection. Foundation.
- 7 A. I don't remember.
- 8 Q. (By Mr. Faes) Do you believe it would be
- 9 inappropriate at this time in 2003, given Actig's
- indication, to be developing efficacy data outside of
- 11 breakthrough cancer pain for marketing purposes?
- MR. MAIER: Objection. Form.
- 13 A. That's two different questions again.
- Q. (By Mr. Faes) Let me restate.
- 15 A. Clinical studies and marketing are two
- 16 different things. Now, reask your question.
- Q. Given Actiq's indication in 2003, which
- 18 was for breakthrough cancer pain only --
- A. Uh-huh.
- 20 O. -- do you believe it would be
- 21 inappropriate to be developing data outside of
- 22 breakthrough cancer pain for marketing purposes?
- MR. MAIER: Objection. Form.
- A. You're still asking two different

- 1 questions. I'm sorry.
- Q. (By Mr. Faes) Would you agree with me --
- A. Ask me marketing or sales.
- 4 Q. All right. I'll withdraw that question.
- 5 My -- how about -- let me start over. Would you agree
- 6 that it would be inappropriate this -- inappropriate at
- 7 this time in 2003, given Actiq's indication to use
- 8 efficacy data outside of breakthrough cancer pain in
- 9 promotional efforts?
- 10 A. Yes.
- MR. MAIER: Objection. Form.
- 12 A. Better question.
- Q. (By Mr. Faes) Okay. You can set that
- document aside and we'll move on. Are you doing okay?
- 15 I think we've been going about an hour-and-a-half.
- MR. MAIER: Hour-and-a-half.
- 17 Q. (By Mr. Faes) You want to take a quick --
- 18 A. How much more is there?
- 19 Q. (By Mr. Faes) It's hard to say. It's
- 20 getting to be about lunchtime too. I don't know if we
- 21 want to break for lunch or --
- A. No. You guys can eat here and ask
- 23 questions.
- Q. Okay. Do you want to keep going or do you

- want to take a quick five-minute break?
- 2 MR. BERG: Do you want to keep going or
- 3 you want to take a --
- 4 A. Yeah, let's do another 10, 15 minutes,
- 5 then I got to go potty.
- 6 Q. (By Mr. Faes) Okay.
- 7 A. If you guys -- I mean, it's up to you guys
- 8 what you want to do.
- 9 MR. BERG: Let's go.
- 10 A. I'm okay with that.
- 11 Q. (By Mr. Faes) So I'm going to hand you --
- 12 I'm going to hand you what's been marked --
- 13 A. Can I grab him for a minute?
- MR. FAES: Yeah. Let's just take a quick
- 15 five-minute break.
- 16 A. Okay. Fine.
- MR. FAES: I need to use the restroom
- 18 anyway, so --
- THE VIDEOGRAPHER: We are going off the
- 20 record at --
- MR. FAES: We don't need to take a long
- 22 one.
- A. If you need to do it, you can ask.
- THE VIDEOGRAPHER: We are going off the

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record at 12:17 PM.
 1
 2
                  [A brief recess was taken.]
 3
                  THE VIDEOGRAPHER: We are back on the
    record at 12:29 PM.
 4
 5
            Q.
                  (By Mr. Faes) Ms. Kaisen, we're back on
 6
     the record after a short break. Are you ready to
 7
    proceed?
 8
            Α.
                  Yes.
 9
                  Before we went on break, Ms. Kaisen, we
10
    were discussing various Actiq marketing plans in the
11
     early years, in 2002 and 2003. Do you remember that?
12
            Α.
                  Yes.
13
                  I'm going to hand you what's been marked
            Q.
14
     as Exhibit Number 9 to your deposition.
15
                  [Exhibit Teva-Kaisen-009
16
                  marked for identification.]
17
                  And this is the two thousand --
            Q.
18
                  UNIDENTIFIED WOMAN: I'm sorry. Could
19
     someone unmute the phone, please, if you're back on the
20
     record?
21
                  [Discussion off the record.]
22
            Q.
                  (By Mr. Faes) So for the benefit of the
23
    people on the phone, I've just handed Ms. Kaisen what's
24
    been marked as Exhibit Number 9 to the deposition, and
```

- 1 this is a document titled 2004 Actiq marketing plan.
- 2 Do you see that, Ms. Kaisen?
- 3 A. I do.
- 4 Q. And I only want to -- you'll be happy to
- 5 know I only want to ask you about one thing in this
- 6 document. If you could turn to Page 30 of this
- 7 document. And if you look on this page, it's a page --
- 8 A. Hang on. Hang on.
- 9 Q. Okay.
- 10 A. Okay. Got it.
- 11 Q. If you look on this page, it's a page
- 12 entitled SWOT analysis and key marketing issues, Actiq
- 13 SWOT analysis; right?
- 14 A. Okay.
- Q. And SWOT stands for strengths, weaknesses,
- opportunities, and threatens; right?
- 17 A. Okay.
- 18 Q. And if you look under opportunities, one
- of the opportunities listed in this 2004 Actiq
- 20 marketing plan are physician eagerness to evaluate
- 21 drugs outside of breakthrough cancer pain. Creates
- 22 opportunities to generate data in needed areas. Do you
- 23 see that?
- 24 A. I do.

- 1 Q. Do you remember that being communicated to
- 2 you as a sales representative in 2004 that physician
- 3 eagerness to evaluate the drug Actiq outside of
- 4 breakthrough cancer pain was an opportunity?
- 5 A. I do not remember this.
- 6 Q. Do you feel it would be inappropriate for
- 7 the company to view that as a strategic opportunity at
- 8 that time, given Actiq's indication?
- 9 MR. MAIER: Objection. Form.
- 10 A. Qualify -- I don't think this was
- 11 something -- I don't know if this was disseminated to
- 12 the sales force or this was the marketing plan that was
- internal, because I don't remember.
- Q. (By Mr. Faes) Understood. Let me ask you
- 15 this. Do you remember the company -- well, strike
- 16 that. At this time in 2004 when you were promoting
- 17 Actiq, were you ever informed that the company was in
- trouble with the FDA for promoting Actiq off label?
- 19 A. I don't remember.
- MR. MAIER: Objection. Form.
- 21 Q. (By Mr. Faes) I'm going to hand you
- 22 what's been marked as Exhibit -- I'm going to hand you
- 23 what's been marked as Ex --
- 24 A. Can I close it?

- 1 Q. You can set that aside. I'm going to hand
- 2 you what's been marked as Exhibit Number 10 to your
- 3 deposition.
- 4 [Exhibit Teva-Kaisen-010
- 5 marked for identification.]
- 6 MR. FAES: Mike, this is 45.
- 7 Q. (By Mr. Faes) And this is a document from
- 8 the FDA. It's a letter from the FDA to Carol Marchione
- 9 at Cephalon, Inc. Do you see that?
- 10 A. Yes.
- 11 Q. Transmitted by facsimile. And it states
- dear Marchione, please refer to the meeting between
- 13 representatives from your firm and DDMAC on August
- 14 30th, 2004. The purpose of this meeting was to discuss
- 15 Cephalon's concern with the DDMAC review process for
- 16 Actiq and to discuss DDMAC's concern with Cephalon's
- 17 promotional activities for Actiq. Do you see that?
- 18 A. I do.
- 19 Q. And you know that DDMAC -- from your long
- 20 experience working in the pharmaceutical industry, you
- 21 know what DDMAC is; right? You know that's the
- 22 enforcement arm of the FDA; right?
- 23 A. Uh-huh.
- Q. And if you turn to the second page of this

- 1 document, this reflects that these are industry meeting
- 2 minutes held on August 30th, 2004, and it looks like a
- 3 number of Cephalon representatives were there,
- 4 including a senior vice-president of pharmaceutical
- 5 operations, Robert P. Roche. Do you see that?
- A. Yeah.
- 7 Q. And Andy Pyfer, and you know he would have
- 8 been the active product director at that time?
- 9 A. Okay.
- 10 Q. Would you -- would Andy Pyfer have been
- one of your superiors at this time?
- 12 A. Yes.
- Q. Did you have contact with Mr. Pyfer?
- 14 A. In what --
- 15 O. Direct contact?
- 16 A. I don't remember.
- 17 Q. You -- did you ever -- you didn't ever
- 18 report directly to him, though; right?
- 19 A. That's a better question. No.
- Q. So if you turn to the page in this
- 21 document ending in 4982.
- 22 A. I just want to clarify. When you say
- 23 representatives of the company, I'm thinking of sales
- 24 representatives. So if you could verbalize upper

- 1 management or sales representatives, I would appreciate
- that, because when opening this document I thought I
- 3 was going to see sales rep names.
- 4 Q. (By Mr. Faes) Okay. So to be fair, if
- 5 you go back to Page 2, these were -- these people that
- 6 were attending this meeting with the FDA on behalf of
- 7 Cephalon -- these were senior people; right?
- 8 A. Yes.
- 9 Q. These are -- these are all people that
- 10 were above you --
- 11 A. Yes.
- 12 Q. -- at Cephalon; right?
- 13 A. Let the record note I've never seen this
- 14 document.
- Q. Okay. If you can turn to the page ending
- 16 in 4982.
- 17 A. Okay.
- 18 Q. And if you look at Paragraph 4, it's --
- one of the notes is that DDMAC expressed concerns that,
- 20 as indicated by Cephalon's briefing package for and
- 21 presentation for the July 14th, 2014, meeting, the
- 22 company is training its sales force to detail doctors
- in a manner that elicits off-label inquiries and to
- 24 respond inappropriately to those inquiries from doctors

- 1 regarding off-label use. Do you see that?
- 2 A. I see it.
- 3 Q. And you --
- 4 MR. MAIER: So the -- sorry. So the
- 5 record is clear, you said 2014. It's 2004.
- 6 A. Thank you.
- 7 MR. FAES: All right.
- MR. MAIER: Just so --
- 9 MR. FAES: I'd better restate it.
- MR. BERG: That's fine. We'll stipulate
- 11 that the document speaks for itself.
- MR. FAES: Well, I don't know if you can
- do that unless counsel wants to speak for it.
- MR. BERG: Okay.
- MR. MAIER: Would you just ask the
- 16 question again --
- MR. FAES: Okay.
- 18 Q. (By Mr. Faes) So starting in Paragraph
- 19 Number 4, it states that DDMAC expressed concerns that,
- 20 as indicated by Cephalon's briefing package for and
- 21 presentation at the July 14th, 2004, meeting, the
- 22 company is training its sales force to detail doctors
- in a manner that elicits off-label inquiries and to
- 24 respond inappropriately to those inquiries from doctors

- 1 regarding off-label use. Do you see that?
- 2 A. I see it.
- Q. And you mentioned earlier that you've
- 4 actually never seen this document before; right?
- 5 A. I don't --
- 6 O. Is thi --
- 7 A. I don't remember this at all.
- 8 Q. Is this information that anyone -- any of
- 9 your superiors ever gave to you at Cephalon, that the
- 10 FDA felt that its sales representatives were detailing
- 11 Actiq inappropriately with regard to off-label use?
- MR. MAIER: Objection. Form, foundation.
- 13 A. I don't remember.
- Q. (By Mr. Faes) If you had received this
- 15 kind of information, that probably would have stuck out
- 16 in your mind; right?
- 17 A. Yes.
- MR. MAIER: Objection. Form.
- 19 Q. (By Mr. Faes) And you probably would have
- 20 wanted to correct those concerns; right?
- 21 MR. MAIER: Objection. Form.
- 22 A. Yes.
- Q. (By Mr. Faes) Because you want to be in
- 24 compliance with the law; right?

- 1 A. Yes.
- 2 Q. So if this was communicated by the FDA to
- 3 the company, you would want somebody to give you this
- 4 information; right?
- 5 A. Yes.
- 6 Q. And as you sit here today, you can't
- 7 remember anybody ever telling you this; right?
- MR. MAIER: Objection. Form.
- 9 A. I'm not saying that. I'm saying I've
- 10 never seen this document.
- 11 Q. (By Mr. Faes) But you also as you sit
- 12 here today don't remember anyone ever tell -- ever
- 13 giving you this information verbally or in any other
- 14 form; right?
- 15 A. I don't remember.
- Q. So is that a yes, you don't -- that was
- what the question was, do you remember anybody ever
- 18 giving you this information?
- 19 A. No.
- 20 O. DDMAC -- if you go it says DDMAC indicated
- 21 that Cephalon's apparent practice of training its
- 22 representatives to broadly discuss breakthrough pain in
- 23 sales calls appears to invite or solicit questions from
- 24 physicians regarding off-label use of the product. Do

- 1 you see that?
- 2 A. I do.
- MR. MAIER: Objection. Form.
- 4 Q. (By Mr. Faes) Did anyone at Cephalon --
- 5 anyone that was above you or supervising -- ever tell
- 6 you that the enforcement arm of the FDA, DDMAC,
- 7 believed that the training for its Actiq
- 8 representatives gave rise to the practice of discussing
- 9 it off-label?
- 10 MR. MAIER: Objection. Form.
- 11 A. I don't remember.
- Q. (By Mr. Faes) But again, if someone had
- 13 told you that, that probably would have stuck out in
- 14 your mind; right?
- MR. MAIER: Objection. Form.
- 16 A. I always followed the letter of the law.
- 17 So I don't know how to answer your question. I mean,
- 18 I've never seen this. I don't remember them saying it
- 19 to me. I don't know if they did or they didn't. I
- 20 don't remember.
- 21 Q. (By Mr. Faes) But you'd agree that if you
- were -- someone at the company in 2004 had come to you
- 23 and said Ms. Kaisen, the FDA has come to us and told us
- 24 that they believe that Actiq is being promoted in a

- 1 manner that suggests off-label use and we need to
- 2 retrain you and change your practices, you probably
- 3 would have remembered that; right?
- 4 MR. MAIER: Objection. Form, foundation.
- 5 A. That was a long time ago. I would have
- 6 if -- I don't remember. I don't know what you want. I
- 7 don't remember. If they did, I would have done to the
- 8 letter of the law, period.
- 9 Q. (By Mr. Faes) And you would have wanted
- 10 to know that information because you would have wanted
- 11 to comply with the law; right?
- 12 A. How I did my sales representing was always
- 13 breakthrough cancer pain, period.
- Q. Right. I understand that, but this is
- 15 communication from the FDA stating that in two -- as of
- 16 2004 they believed that the way Actiq sales
- 17 representatives are doing their sales call suggests
- 18 off-label use; right? That's what this says?
- 19 A. Yes.
- 20 Q. And like I said, no -- you don't remember
- 21 anybody ever telling that and you would want to know
- 22 that; right?
- MR. MAIER: Objection. Form.
- A. I don't remember.

- 1 Q. (By Mr. Faes) If you go on to the fourth
- line up, it reads DDMAC stated that although responses
- 3 to off-label questions provided in the sales training
- 4 materials include a statement of the indication, no
- 5 risk information is provided regarding the off-label
- 6 use, and moreover, the rest of the response appears to
- 7 suggest a strong medical basis for and encourage
- 8 off-label use, which is concerning, especially given
- 9 the RMP, which means risk management program; right?
- 10 A. Uh-huh.
- 11 Q. Did anyone ever come to you in 2004 and
- 12 tell you that the response question suggested in
- 13 materials -- training materials that were used -- being
- 14 used for Actiq suggested for and encouraged off-label
- use according to the FDA?
- MR. MAIER: Objection. Form.
- 17 A. I don't remember. I see it, but I don't
- 18 remember.
- 19 Q. (By Mr. Faes) You don't remember them
- 20 ever giving you this information; right?
- 21 A. I don't.
- Q. And this is information that you would
- have wanted in order to comply with the law; right?
- MR. MAIER: Objection. Form.

- 1 A. Somehow I feel he's leading.
- MR. BERG: There's no -- all right.
- A. He's leading me to say something I'm
- 4 not --
- 5 MR. BERG: Right. Let me just object to
- 6 the form as well. I think the deponent's concern is
- 7 that you're accusing her of doing something illegal,
- 8 and I think probably she needs to be reassured that's
- 9 not the question.
- 10 A. I feel like it's a --
- 11 Q. (By Mr. Faes) Right. I mean, we've --
- 12 A. It's a leading question, and I --
- MR. BERG: Well, no, he can ask a leading
- 14 question, but just --
- 15 A. I just -- I don't -- how many times do I
- 16 have to tell him I don't remember this?
- Q. (By Mr. Faes) My question is, you would
- have wanted to know this information; right?
- 19 A. Yes.
- 20 Q. And assuming that Cephalon didn't give you
- 21 this information, that would have prevented you from
- 22 doing your job properly and following the letter of the
- 23 law; right?
- MR. MAIER: Objection. Form, foundation.

- 1 A. I don't remember if they did or they
- 2 didn't.
- 3 Q. (By Mr. Faes) Right. I understand that.
- 4 But I'm asking a hypothetical.
- 5 A. Oh.
- 6 Q. I'm allowed to do that. So assuming --
- 7 since you can't remember, assuming that Cephalon never
- 8 gave you this information, that that would have
- 9 prevented you from doing your job as a sales
- 10 representative and following the letter of the law;
- 11 right?
- MR. MAIER: Objection. Form, foundation.
- 13 A. Restate that, please.
- Q. (By Mr. Faes) Assuming that Cephalon
- 15 never gave you this information listed in Paragraph 4
- of this document, that would have prevented you from
- 17 effectively doing your job as a sales representative;
- 18 right?
- MR. MAIER: Objection. Form, foundation.
- A. Help me out with this.
- 21 MR. BERG: He's asking you, do you feel
- 22 that not having this information would have affected
- you to do your job and follow the law?
- MR. FAES: Well, actually I changed it and

I didn't have follow the law. 1 2 MR. BERG: Okay. 3 MR. FAES: Do you need me to ask the question again? I'm not trying to --4 5 MR. BERG: I think it's assuming she's not following the law to begin with. 6 7 MR. FAES: Well, I didn't ask it that 8 way --9 MR. BERG: Well -- okay. 10 MR. FAES: -- so let me ask it again. 11 Α. But --12 (By Mr. Faes) Assuming --Ο. I don't mean to be difficult, but I don't 13 Α. 14 remember this given to me, and if you say that it was 15 given to me or if it was going to give it to me -- yes, 16 I always do the legal thing, period. 17 (By Mr. Faes) Right. So my question Q. is --18 19 MR. BERG: Okay. 20 (By Mr. Faes) If Cephalon didn't give you Ο. the information listed in Paragraph 4 of this letter, 21 22 would that have prevented you from doing your job 23 effectively as a sales rep?

MR. MAIER: Objection. Form, foundation.

24

- 1 A. Whether they did or didn't give that to
- 2 me, I would have still followed breakthrough cancer
- 3 pain and not sold off-label, period. Does that answer
- 4 your question?
- 5 Q. (By Mr. Faes) Sure. But I mean, if the
- 6 FDA believed that Cephalon was doing something wrong
- 7 currently in 2004 with regard to its promotion of
- 8 Actiq, you would want to know that; right?
- 9 A. Yes.
- 10 Q. Okay. You can set that document aside.
- 11 So I'm going to hand you what's been marked as Exhibit
- 12 Number 7 to your deposition. No, it's not.
- MR. FAES: It's 7 for you, Mike.
- Q. (By Mr. Faes) I'm going to hand you
- what's been marked as Exhibit Number 11 to your
- 16 deposition.
- 17 [Exhibit Teva-Kaisen-011
- marked for identification.
- 19 A. 2005. Is this yours or mine?
- Q. That's yours. You get the one with --
- 21 always get the one with the sticker.
- 22 A. Oh.
- Q. And I usually give you yours first. And
- 24 doc -- or where are we? What exhibit are we on?

- 1 Exhibit Number 11 is a document entitled 2005 Actiq
- 2 marketing plan. Do you see that?
- A. Hang on. Just looking to see who is on
- 4 the -- who the people were. Yeah. Yes. Thank you.
- Q. Yeah. And since you're looking at that,
- 6 the first name listed is Andy Pyfer, and he would have
- 7 been the product director for Actiq at this time;
- 8 right?
- 9 A. Okay.
- 10 Q. And he would have been one of your
- 11 superiors at the company; right?
- 12 A. Yes.
- Q. And again, this document has the old
- 14 familiar bell on the front of it that you're familiar
- 15 with; right?
- 16 A. Yes.
- 17 Q. And if you turn to Page 2 of this
- document, which I believe is actually the third page in
- because you're not counting the cover, and under
- 20 executive summary it states 2004, performance review.
- 21 And it says in 2004 Actiq continued its growth;
- 22 however, not at the same rate as in prior years. Actiq
- 23 sales for 2004 will likely fall short of the budget
- 24 number of \$416 million with a forecast number of \$387

- 1 million in gross shipments. Do you see that?
- 2 A. Uh-huh.
- Q. Is that consistent with your memory with
- 4 regard to the performance of Actiq in 2004?
- 5 MR. MAIER: Objection. Form, foundation.
- 6 A. I honestly don't remember.
- 7 Q. (By Mr. Faes) Is this information that
- 8 would have been shared with you as part of your job as
- 9 a sales representative as the overall sales of the
- 10 products that you were working on?
- 11 A. Overall sales would be shared with us,
- 12 yes. This document I'm not so sure.
- 13 Q. But you have no reason to dispute these
- 14 numbers as we went over --
- 15 A. Because I don't remember --
- 16 Q. -- on this page of the document?
- 17 A. I don't remember them.
- 18 Q. Okay. So if you go to Page 6 of this
- 19 document.
- 20 A. Okay.
- Q. Do you see there's external factors listed
- 22 with regard to Actiq, and the first one is negative
- 23 media attention? There has been an increase in the
- volume of press coverage around Actiq and other

- 1 opioids. This coverage is centered mainly on cases of
- 2 abuse and diversion. Do you see that?
- 3 A. Uh-huh.
- 4 Q. Is that something you remember occurring
- 5 at this time in 2005 with regard to Actiq, that there
- 6 was increased negative media attention?
- 7 A. I don't remember.
- Q. As you sit here, do you have any reason to
- 9 believe that the information reported in this 2005
- 10 Actiq marketing plan isn't true?
- 11 A. No, because I don't think I was privy to
- 12 it.
- 13 Q. So you don't think that you were privy to
- 14 the marketing plans of the company as a sales
- 15 representative out in the field who was responsible for
- 16 executing those plans?
- 17 A. That's not what I said. That's not what I
- 18 said. This -- the marketing plan, yes, we had to
- 19 follow the marketing plan. However, the extent in this
- 20 document I don't remember. This whole entire
- 21 document -- I don't remember seeing this or remember
- 22 it.
- Q. So irrespective of the document -- let's
- 24 put the document aside.

- 1 A. Okay.
- 2 Q. The document is just a guide really meant
- 3 to help you remember what was occurring at this time
- 4 because it was a long time ago. So my question is, is
- 5 it true that in 2005 there was an increase in the
- 6 volume of press coverage around Actiq and other opioids
- 7 and that that coverage centered mainly on cases of
- 8 abuse and diversion?
- 9 MR. MAIER: Objection. Foundation.
- 10 A. I don't remember.
- 11 Q. (By Mr. Faes) Is it true that in 2005
- there were DDMAC criticisms of promotional materials?
- 13 A. I don't remember.
- 14 MR. MAIER: Objection. Foundation.
- 0. (By Mr. Faes) And that was -- that's
- 16 referring to the document that we just looked at
- 17 previously that was discussing those concerns; right?
- 18 A. Right.
- 19 O. And if there had been DDMAC criticisms of
- 20 promotional materials, you would have wanted to know
- 21 about those concerns; right?
- 22 A. Yes.
- 23 Q. And do you remember ever being told about
- 24 any DDMAC or FDA concerns with any of the promotional

- 1 materials you were using for Actiq?
- MR. MAIER: Objection. Form, foundation.
- 3 A. I don't remember.
- 4 Q. (By Mr. Faes) Do you remember anyone ever
- 5 coming to you in the field and saying, hey, we need to
- 6 stop using these promotional materials because the FDA
- 7 has criticisms of them?
- MR. MAIER: Objection. Form.
- 9 A. I remember something about the bell and
- 10 that they had to take everything off the literature,
- 11 and that's just the back of my mind.
- 12 Q. (By Mr. Faes) So do you remember that
- there were apparently some concerns from the FDA about
- 14 materials related to Actiq; you just don't remember
- 15 specifically what they were?
- 16 A. Yes.
- 17 MR. MAIER: Objection. Form. Misstates
- 18 testimony.
- 19 Q. (By Mr. Faes) Do you remember at this
- 20 time in 2005 that there was a growing opiophobia,
- 21 meaning concerns of abuse, addiction, and diversion,
- 22 among physicians, patients, and member of the general
- 23 public?
- MR. MAIER: Objection. Foundation.

- 1 A. In 2005?
- Q. (By Mr. Faes) Uh-huh.
- 3 A. Okay. This has been occurring a lot
- 4 earlier than 2005. So am I aware of it then?
- 5 Q. But do you remember growing concerns about
- 6 opiophobia?
- 7 MR. MAIER: Objection --
- 8 A. I don't remember at that time growing
- 9 concerns or not. I just remember that it always has
- 10 been a concern.
- 11 Q. (By Mr. Faes) Do you have any reason to
- 12 believe that this is untrue -- what's reported in this
- 13 2005 marketing plan, that there was growing concern of
- 14 opiophobia?
- 15 A. No.
- Q. What's your understanding of what
- 17 opiophobia is?
- 18 A. First of all, I've never heard the term
- 19 opiophobia.
- 20 O. Never before --
- 21 A. I don't remember opiophobia.
- 22 Q. Be --
- A. Now, people who are afraid of opioids, but
- 24 I've never heard it called opiophobia. People who are

- 1 afraid -- it's the same thing -- who are afraid of
- 2 opioids because they're afraid that they are going to
- 3 become addicted. So the cancer patients -- we would
- 4 have a tough time with cancer patients taking enough
- 5 meds to get them out of pain because they were afraid
- 6 they were going to get addicted even though they were
- 7 going to die in three, four months.
- 8 So when you have a fear, that's what I'm
- 9 thinking of, is opiophobia. I've never heard op -- now
- 10 I'm feeling like I didn't get trained correctly, but
- 11 opiophobia -- I know what it means, but I've never
- 12 heard it by the company, I don't think.
- Q. So it's your testimony that in 15 years
- 14 detailing Actig and Fentora --
- 15 A. Oh, geez.
- 16 Q. -- you've never heard the term
- 17 opiophobia?
- 18 MR. MAIER: Objection. Form.
- 19 A. I don't remember.
- 20 O. (By Mr. Faes) Okay. So if you turn to
- 21 Page 25 of this document. It states that -- up there
- 22 at the very top it states that based on physician
- 23 reporting, 90 percent of Actiq use is for BTP or
- 24 breakthrough pain outside of cancer with the majority

- of use, 55 percent of total, being for chronic back
- 2 pain. This broad use of Actiq suggests there might be
- 3 prescribers who understand or are experienced
- 4 prescribing fentanyl, treat the pain pathophysiology,
- 5 not the disease state or etiology, understand the
- 6 benefits Actiq affords their patients, are comfortable
- 7 utilizing it belong -- beyond its labeled indication.
- 8 Do you see that?
- 9 A. I do.
- 10 Q. Do you remember at this time in 2005 that
- 11 the company had data indicating that 90 percent of
- 12 Actiq use is for breakthrough pain outside of cancer?
- MR. MAIER: Objection. Foundation.
- 14 A. I don't remember that statement.
- Q. (By Mr. Faes) Is that -- do you have any
- 16 reason to believe that that statement isn't true as
- it's contained in this 2005 marketing plan prepared by
- 18 the company?
- 19 MR. MAIER: Objection. Foundation.
- 20 A. I don't know what they were thinking, but
- 90 percent seems awfully high to me. That seems crazy.
- Q. (By Mr. Faes) Were you ever told that 90
- 23 percent --
- A. I don't remember.

- 1 Q. Let me get the whole question out. Were
- 2 you ever told by the company that in 2005, 90 percent
- 3 of Actiq use was for breakthrough pain outside of
- 4 cancer?
- 5 MR. MAIER: Objection. Form.
- 6 A. I don't remember that.
- 7 Q. (By Mr. Faes) And you'd agree with me --
- 8 well, strike that. If that was data that was true and
- 9 the company knew that, is that information you would
- 10 have wanted to know?
- 11 A. Yeah.
- 12 Q. And we can agree that Actiq use for
- 13 breakthrough pain outside of cancer is illegal; right?
- 14 A. Yes.
- MR. MAIER: Objection. Form.
- Q. (By Mr. Faes) Yeah, that's actually a bad
- 17 question. We can agree that breakthrough -- strike
- 18 that. We can agree that the use of Actiq for
- 19 breakthrough pain outside of cancer is off-label;
- 20 right?
- 21 A. Better question. Thank you. Yes.
- Q. And it's actually -- if you want to go
- 23 back and correct that -- it's not actually illegal; it
- 24 would just be illegal to promote it off-label; right?

- 1 A. Exactly.
- 2 Q. So a doctor can prescribe it off-label and
- 3 it's not necessarily illegal; right?
- 4 A. Yes.
- 5 Q. Now I'm going to take a second here. This
- 6 is actually to your benefit because the clock is
- 7 running and I'm trying to cut this down a little bit;
- 8 okay? So if you can turn to Page 44 on this document,
- 9 there's just one more thing I want to ask about --
- 10 A. Just looking at -- never --
- 11 Q. -- ask you about this and then we'll set
- 12 it aside.
- 13 A. Yeah.
- 14 Q. On Page 44 in about the center of the
- document it states that there has been increased
- 16 scrutiny by the FDA on Actiq's use and they have
- 17 expressed concerns with the growing reports of abuse
- 18 mis -- and misuse of the product. Do you see that?
- 19 A. I do.
- Q. Is that consistent with your memory that
- 21 in 2005 there were growing concerns about abuse and
- 22 misuse of Actiq?
- MR. MAIER: Objection. Form.
- A. I don't remember.

- 1 Q. (By Mr. Faes) You can set that document
- 2 aside, and actually what I'm going to have you do is if
- 3 you can dig out --
- 4 A. Uh-oh.
- 5 Q. Well, before you do that, let me just ask
- 6 you this. During your time promoting Actiq, you did
- 7 become aware that sometimes some of the physicians that
- 8 you called on did promote -- or strike that. You would
- 9 agree with me that during your time promoting Actiq you
- 10 became aware that some of your physicians would
- 11 sometimes prescribe Actiq off-label; right?
- 12 A. Yes.
- Q. And if I can have you pull out Exhibit 3
- 14 out of that stack, which is your call notes.
- 15 A. I'm getting stuck. Yeah. Okay.
- 16 Q. So I just want to ask you about a couple
- of things on this. If you look at the very first page
- 18 on the fifth entry from the bottom. You see you've got
- 19 a call to Dr. James Bressi on 6-13-01?
- 20 A. Okay.
- Q. And if you look in your call comments, you
- 22 noted --
- 23 A. Uh-huh.
- Q. -- that you discussed Actiq for

- 1 breakthrough cancer pain. He is mad about Ohio
- 2 Medicare. Five PTS, which I assume mean patients, got
- 3 turned down this week for not having breakthrough
- 4 cancer pain. He wants the person at O.Med he can write
- 5 a letter to. Do you see that?
- 6 A. I do.
- 7 Q. And this would have been a call note
- 8 entered by you?
- 9 A. Yes.
- 10 Q. And this note would indicate that at this
- 11 time, at least five of Dr. Bressi's patients were being
- 12 prescribed Actiq off-label; right?
- MR. MAIER: Objection. Form.
- 14 A. Yes.
- Q. (By Mr. Faes) And this is early on with
- 16 your time with the company; right? This is in June of
- 17 2001?
- 18 A. If you say so. Is it -- what's the date?
- 19 Q. Well, you can look at the call date.
- 20 6-13-2001.
- 21 A. Okay.
- Q. And so that would be about four months
- after you started with the company; right?
- 24 A. Yes.

- 1 Q. And unfortunately these aren't labeled,
- 2 but if you can -- don't have page numbers, but if you
- 3 can turn to Page 11. And it might be easier for you to
- 4 follow along on the screen. And if you look at the
- 5 fourth entry down, this is -- you note that you've made
- 6 a call note on August 31st of 2001. And what's that
- 7 doctor's name? Antoine --
- A. I'm not there yet.
- 9 Q. Okay. I'll let you read the doctor's name
- 10 because you're probably better than me.
- 11 A. I don't remember him. Chahine.
- 12 Q. Okay. Well, we'll just do the best we can
- 13 with the pronunciation.
- 14 A. He's an oncologist.
- O. Right. So this is a note to Dr. Antoine
- 16 Chahine, who you say is an oncologist --
- 17 A. Uh-huh. Right there.
- 18 Q. -- on August 31st of 2001. And the call
- 19 comments note discussed Actiq with breakthrough pain
- 20 with Dr. Eldab. He is very interested in using in his
- 21 head and neck patients. Do you see that?
- 22 A. I do.
- Q. And you'd agree with me that even for a
- 24 cancer doctor, prescribing Actiq for the indication of

- 1 head or neck pain would be an off-label use; right?
- 2 MR. MAIER: Objection. Form.
- A. Head or neck patients with cancer. Head
- 4 cancer, neck -- head and neck cancer.
- 5 Q. (By Mr. Faes) Okay. Fair enough. If you
- 6 turn to Page 13 of this document, and we're looking at
- 7 the one -- the entry that's -- one, two, three, four,
- 8 five, six, seven -- we're looking at the entry that's
- 9 eight from the bottom.
- 10 A. Hang on.
- 11 Q. Yeah, it's hard to read, isn't it?
- 12 A. Yeah. Okay.
- 13 Q. So this is another call --
- A. Oncologist.
- 15 Q. This is another call note dated April 30th
- of 2001 entered by you, and again this is Dr. Eric
- 17 Chevlen?
- A. Uh-huh.
- 19 Q. And it sta -- again it states discussed
- 20 Actiq for breakthrough cancer pain. He says he uses it
- on his head and neck patients. I tried to expand this
- 22 to other patients with breakthrough cancer pain. Do
- 23 you see that?
- A. Yes. Head and neck cancer patients.

- 1 Q. So that doesn't indicate to you that Dr.
- 2 Chevlen could have been using it on head and neck
- 3 patients that didn't have breakthrough cancer pain,
- 4 that didn't have cancer?
- 5 MR. MAIER: Objection. Form.
- 6 A. Only with cancer. Head and neck cancer.
- 7 Q. (By Mr. Faes) If I can have you turn to
- 8 Page 17 of this document. You're looking at the fourth
- 9 entry from the top, and this --
- MR. FAES: Huh?
- MS. JAIN: Fourth from the bottom.
- MR. FAES: Fourth from the bottom. Thank
- 13 you.
- Q. (By Mr. Faes) We're looking at the --
- we're on Page 17 of this document. We're looking at
- 16 fourth entry from the bottom.
- 17 A. Uh-huh.
- 18 Q. And this is an entry dated August 10th of
- 19 2001, and this is on a Dr. Jerome Yokiel?
- A. Yokiel.
- Q. And the call comment is that you discussed
- 22 Actiq for breakthrough pain at a lunch and learn. He
- 23 told me he was having great success for migraines. Do
- 24 you see that?

- 1 A. Yes, but I have to back you up, because
- 2 I'm not going to answer that question, because you keep
- 3 saying breakthrough pain, and it's breakthrough cancer
- 4 pain, and I want to be very strict with that when you
- 5 ask me those questions.
- 6 O. Oh, that's my fault. Let me reask the
- 7 question.
- 8 A. Thank you.
- 9 Q. So this call note dated 8-10-2001, you
- 10 state discussed Actiq for breakthrough cancer pain at a
- 11 lunch and learn. He told me he was having great
- 12 success for migraines. Do you see that?
- 13 A. I do.
- Q. And this would be a call note that would
- 15 have been entered by you in August of 2001; right?
- 16 A. Okay.
- Q. And you noted that Dr. Yokiel was having
- 18 success with Actiq for migraines; right?
- 19 A. Okay.
- 20 O. And that would have been an off-label use;
- 21 right?
- 22 A. Yes. Which would have been followed up
- 23 with a medical request form.
- Q. So this is -- these are notes from 2001,

- 1 so we can see that at least as in 2001, which was your
- 2 first year as a representative for Cephalon -- I'm
- 3 going to start over because they're recording
- 4 everything and it's just going to sound awful. So
- 5 these are notes from 2001, and you can see that during
- 6 your first year at Cephalon you were aware of at least
- 7 two doctors that were prescribing Actiq for off-label
- 8 use; right?
- 9 MR. MAIER: Objection. Form.
- 10 A. Not two. Where's the other one? You said
- 11 head and neck cancer.
- 12 Q. (By Mr. Faes) Dr. Bressi and Dr. Yokiel.
- 13 Remember Dr. Bressi was -- had five patients that got
- 14 turned down for not having breakthrough cancer pain?
- 15 A. Okay.
- Q. And Dr. Yokiel was using it for migraines;
- 17 right?
- MR. MAIER: Objection. Form, foundation.
- 19 A. That's true.
- 20 O. (By Mr. Faes) Right. And so we know --
- 21 and we know that there's at least six patients in your
- 22 category that are getting it off-label, because Dr.
- 23 Bressi had five and Dr. Yokiel must have had at least
- one if he was using it for migraines; right?

- 1 MR. MAIER: Objection. Form, foundation.
- 2 A. Yes.
- Q. (By Mr. Faes) And we know that eventually
- 4 you weren't allowed to enter the kind of call comments
- 5 that we're seeing here in Exhibit Number 3 because the
- 6 company changed the policy on the way that call
- 7 comments were allowed to be entered; right?
- MR. MAIER: Objection. Form, foundation.
- 9 A. The industry, yes.
- 10 Q. (By Mr. Faes) And that was done for
- 11 liability reasons; right?
- 12 A. I don't know.
- MR. MAIER: Objection. Form, foundation.
- Q. (By Mr. Faes) Well, didn't you testify
- 15 earlier that it was for liability reasons?
- 16 A. You had asked me that question --
- MR. MAIER: Objection. Form.
- 18 A. -- and I said yes, that could be one of
- 19 the reasons -- liability. It wasn't the only reason.
- O. (By Mr. Faes) Well, what were some --
- 21 A. I don't know what the other reasons were.
- 22 It could have -- so liability could have been one of
- 23 them, so I answered yes.
- 24 Q. Okay.

- 1 A. Your questions need to be more direct.
- 2 Q. And so if you were -- if a situation like
- 3 this were to occur after that change in company policy
- 4 was made to the way call notes were allowed to be
- 5 entered, situations like the ones with Dr. Bressi and
- 6 Dr. Yokiel wouldn't have been recorded at that time;
- 7 right?
- MR. MAIER: Objection. Form.
- 9 Q. (By Mr. Faes) At least not in your call
- 10 notes?
- 11 A. They wouldn't have been in the call notes.
- 12 Q. Now, at some point during your employment
- 13 at Cephalon did you become aware that the company pled
- 14 guilty to promoting Actiq and other drugs off-label in
- 15 violation of the law?
- 16 A. Yes.
- 17 Q. I'm going to hand you what's been marked
- 18 as Exhibit Number 12 to your deposition.
- 19 [Exhibit Teva-Kaisen-012
- 20 marked for identification.]
- 21 MR. FAES: 10.1, Mike.
- Q. (By Mr. Faes) And this is a guilty plea
- 23 agreement between the United States of America and
- 24 Cephalon; right?

- 1 A. Uh-huh.
- 2 Q. And if you look under Section 1 it states
- 3 that Cephalon agrees to plead guilty to one count of
- 4 information, waiving prosecution by indictment,
- 5 charging it with introduction into interstate commerce
- of drugs that were misbranded through off-label
- 7 promotion, a misdemeanor in violation of 21 USC Section
- 8 331. Do you see that?
- 9 A. Where's the date on this?
- 10 Q. Well, if you turn to the second-to-last
- 11 page, you can see that this was signed on September
- 12 15th of 2008 by Gerald Pappert, who's the
- 13 vice-president and general counsel for Cephalon at this
- 14 time; right?
- 15 A. I was trying to get a frame of reference.
- 16 O. Sure.
- 17 A. Thank you. Okay.
- 18 Q. And if you turn back to the first page, it
- 19 states that this is all arising from -- in the third to
- 20 last sentence of the paragraph, this is all arising
- 21 from Cephalon's off-label promotion of its drug
- 22 Provigil, Gabitril, and Actiq between January 2001 and
- October of 2001. Do you see that?
- A. Uh-huh.

- 1 Q. So this -- as we said, this happened in
- 2 September of 2008; right?
- 3 A. Okay.
- 4 Q. And this would have -- was this announced
- 5 within the company, or were you made aware of it?
- 6 A. We were made aware.
- 7 Q. Did any -- are you aware of anyone that
- 8 ever lost their job as a result of this guilty plea?
- 9 MR. MAIER: Objection. Foundation.
- 10 A. I don't remember.
- 11 Q. (By Mr. Faes) Are you aware of any
- 12 disciplinary action ever taken against anyone as a
- 13 result of this guilty plea?
- MR. MAIER: Objection. Foundation.
- 15 A. I don't remember.
- 16 Q. (By Mr. Faes) Are you aware of any
- 17 changes to company policies and procedures that were
- implemented as a result of this guilty plea?
- 19 MR. MAIER: Objection. Foundation.
- A. Are you talking the CIA agreement?
- Q. (By Mr. Faes) Well, I'm asking you, are
- 22 you aware of any changes to company policies and
- 23 procedures?
- A. I just don't know when it was. CIA

- 1 agreement?
- 2 Q. So you believe that there was a corporate
- 3 integrity agreement or CIA agreement that was required
- 4 to be signed as a part of this settlement agreement;
- 5 right?
- 6 A. Yes.
- 7 Q. Were there any other changes to policies
- 8 and procedures that you're aware of that were
- 9 implemented as a result of this guilty plea?
- 10 A. I don't remember.
- 11 Q. I'm going to hand you what's been marked
- 12 as Exhibit Number 15 (sic) to your deposition.
- 13 [Exhibit Teva-Kaisen-013
- marked for identification.]
- MR. FAES: This is 12, Mike, for you.
- 16 O. (By Mr. Faes) This is an e-mail from
- 17 Randy Spokane, and he would have been your boss's boss
- 18 at this time this e-mail was sent in 2006; right?
- 19 A. Yes.
- Q. And the subject of this e-mail is Wall
- 21 Street Journal, 11-21-2006, Cephalon used improper
- 22 tactics. Do you see that?
- 23 A. Yes.
- Q. And this would have been about two years

- 1 before the corporate integrity agreement -- or I'm
- 2 sorry. This would have -- strike that and start over.
- 3 This would have been about two years before the guilty
- 4 plea that we just looked at that was signed in 2008;
- 5 right?
- 6 A. Yes.
- 7 Q. So if you look further down, it states the
- 8 Wall Street Journal continues to cover issues related
- 9 to the promotion of Actiq?
- 10 A. Uh-huh.
- 11 Q. And it appears that there's an article
- 12 from the Wall Street Journal further down. And it
- 13 starts, from setting unrealistically high sales quotas
- 14 to pushing larger prescriptions at higher doses,
- 15 drugmaker Cephalon, Inc., engaged in a questionable
- 16 practice to expand the sales of Actiq, a powerful
- 17 narcotic lollipop approved only to treat cancer pain,
- 18 according to a two-year investigation by the
- 19 Connecticut Attorney General. Do you see that?
- 20 A. I do.
- 21 Q. In 2006, were you aware that in addition
- 22 to being charged with -- by the Department of Justice
- 23 and settling with them in 2008, that Cephalon was also
- 24 under investigation for its promotion of Actiq by the

- 1 Connecticut Attorney General?
- MR. MAIER: Objection. Form, foundation.
- A. I don't remember. I was not copied on
- 4 this either.
- 5 Q. (By Mr. Faes) So your boss's boss never
- 6 felt it necessary to share this information with you?
- 7 MR. MAIER: Objection. Form, foundation.
- A. I don't remember.
- 9 Q. (By Mr. Faes) Let me ask a better
- 10 question. At this time, Randy Spokane would have been
- 11 your boss's boss; right?
- 12 A. Uh-huh.
- Q. And you don't recall ever -- anyone at
- 14 Cephalon ever sharing the information with you that
- 15 Actiq was under investigation by the Connecticut
- 16 Attorney General for questionable promotional tactics
- 17 used with Actiq?
- 18 A. I don't remember.
- 19 Q. And you would have been a sales
- 20 representative promoting and detailing Actig at this
- 21 time; right?
- 22 A. Yes.
- Q. Is this information that you would have
- 24 wanted to know?

- 1 A. I don't know how to answer that question.
- 2 Q. So you don't -- do you know one way or the
- 3 other whether you would want to know this as a person
- 4 distributing Actiq?
- 5 MR. MAIER: Objection. Form.
- A. Help me out here. I don't understand him.
- 7 Q. (By Mr. Faes) Let me strike that and
- 8 reask a different question. If the Connecticut
- 9 Attorney General believed that the tactics being used
- 10 to promote Actiq were illegal and the company was under
- investigation for that, is that something that you
- would have wanted to know as someone who was promoting
- 13 the product in 2006?
- MR. MAIER: Objection. Form, foundation.
- MR. BERG: Is that something you would
- 16 have wanted to know?
- 17 A. I follow what the company tells me. Do I
- 18 want to know this or not know it? Okay. All
- 19 information's good.
- Q. (By Mr. Faes) So the answer is yes, you
- 21 would have liked to have known; right?
- 22 A. Okay.
- Q. And if you go on, it states that people
- 24 familiar with the probe say that among other tactics,

- 1 Cephalon promoted the drug off-label or for nonapproved
- 2 uses to neurologists and touted small studies conducted
- 3 by doctors to whom it had ties in an effort to get
- 4 Actiq prescribed for migraines. In addition, they say,
- 5 Cephalon flew doctors to seminars that promoted Actiq's
- 6 use for headaches and in patients who might not
- 7 tolerate it well. Do you see that?
- 8 A. I do.
- 9 Q. Were you aware when you were promoting
- 10 Actiq at this time in 2006 that these were allegations
- 11 made by the Connecticut Attorney General?
- 12 A. I don't remember.
- 13 Q. If someone had made you aware of that, do
- 14 you think you -- do you think it would have stuck out
- in your mind?
- MR. MAIER: Objection. Form.
- 17 A. At this point I don't remember.
- 18 Q. (By Mr. Faes) Is that information you
- 19 would have wanted to know?
- 20 A. Yes. I mean --
- 21 Q. If you turn to the following page of this
- 22 document. And I'm looking at the sixth paragraph from
- the bottom, and it states in a one-page article in the
- 24 Wall Street Journal earlier this month --

- 1 MR. BERG: Hold on. One second. Do you
- 2 need -- you want to take a break, or do you want him to
- 3 start over with the question?
- 4 A. No. Go ahead.
- 5 Q. (By Mr. Faes) If you look at the sixth
- 6 paragraph from the bottom, it states in a one-page
- 7 article in the Wall Street Journal earlier this month,
- 8 Cephalon acknowledged that it sends sales
- 9 representatives to a broad range of doctors, many of
- 10 whom have nothing to do with cancer. The company says
- 11 such visits are appropriate because cancer visits are
- often treated for pain by noncancer doctors. Do you
- 13 see that?
- 14 A. I do.
- 15 Q. Is that consistent with messaging that you
- 16 would have received as a sales rep for Actiq at this
- 17 time?
- MR. MAIER: Objection. Form.
- 19 A. I don't know what the company has to say,
- 20 but we followed physicians, noncancer doctors, but they
- 21 treated cancer patients.
- Q. (By Mr. Faes) So it's true then that
- 23 you -- it's true what Cephalon says, that it sends
- 24 sales representatives to a broad range of doctors, many

- of whom have nothing to do with cancer?
- MR. MAIER: Objection. Form, foundation.
- 3 Misstates testimony.
- 4 A. Please rephrase. I guess I'm getting
- 5 tired or -- this is --
- 6 Q. (By Mr. Faes) Is it your understanding
- 7 that it was true or not true in 2006 that Cephalon
- 8 would send sales representatives to a broad range of
- 9 doctors, many of whom have nothing to do with cancer?
- 10 MR. MAIER: Objection. Form, foundation.
- 11 A. Can I qualify that?
- MR. BERG: Yeah, you can answer as best
- 13 you can. Yeah.
- 14 A. We were given a list of physicians to call
- on. Did they send me there? I just don't like that
- 16 send thing. Send me there? We would vet them. In
- other words, I would go to the decile and I would ask
- 18 them, did you treat patients with break -- for
- 19 breakthrough cancer pain?
- 0. (By Mr. Faes) So they -- so it's true
- 21 then that they would -- the company would sometimes
- 22 send you to doctors to detail Actiq that had nothing to
- 23 do with cancer?
- MR. MAIER: Objection. Form, foundation.

- 1 A. No comment. I just don't remember. I
- 2 don't know how to answer that question. I just don't
- 3 like the question. I just don't think it's very
- 4 direct.
- 5 Q. (By Mr. Faes) So I'm going to hand you --
- 6 MR. MAIER: You may have accidentally
- 7 skipped Exhibit 13, unless I'm missing something. In
- 8 the numbering, did we go from 12 to 15?
- 9 MS. JAIN: That's 14.
- 10 [Discussion off the record.]
- MR. MAIER: We can just continue. I don't
- 12 want to hold us up.
- Q. (By Mr. Faes) Okay. I'm going to hand
- 14 you what's been marked as Exhibit Number 14 to your
- 15 deposition.
- 16 [Exhibit Teva-Kaisen-014]
- marked for identification.]
- 18 O. And this is another Wall Street Journal
- 19 article that was circulated within the company dated
- November 3rd, 2006. Do you see that?
- 21 A. Well, I wouldn't say it was throughout the
- 22 company. It was to Cynthia Condodina.
- 23 O. Right. And Cynthia Condodina was a person
- 24 within the company; right?

- 1 A. You said throughout the company.
- 2 Q. So this is an article that was distributed
- within the company dated 11-3-2006; right?
- 4 A. Yes.
- 5 Q. And this is from the Wall Street Journal,
- 6 apparently dated November 3rd, 2006; right?
- 7 A. Yes.
- 8 Q. So despite whether or not this was
- 9 circulated within the company or not, this would be an
- 10 article that would be publicly available; right?
- 11 A. Yes.
- 12 Q. And if you look down in the middle
- 13 paragraph next to the picture that isn't there,
- 14 starting with data on the right-hand side, this states
- data gathered from a network of doctors by research
- 16 firm ImpactRx between June 2005 and October 2006
- 17 suggest that 80 percent of patients who use the drug
- don't have cancer. Instead, doctors prescribe it
- off-label for unapproved uses such as headaches or back
- 20 pain. Do you see that?
- 21 A. I do.
- Q. And we saw earlier in the 2005 Actiq
- 23 marketing plan that the company estimated in 2005 that
- the off-label use of Actiq was 90 percent; right?

- 1 A. Uh-huh.
- Q. So this reporting is fairly consistent
- 3 with that; right?
- 4 MR. MAIER: Objection. Form.
- 5 A. I've never seen this. And this is written
- 6 by media. I would need to see the statistics behind
- 7 it. This is media driven. Sorry.
- Q. (By Mr. Faes) Right. But my question
- 9 was, this 80 percent off-label use as reported by the
- 10 media is fairly consistent with the 90 percent figure
- 11 reported --
- 12 A. How do I answer that?
- Q. -- by the company in their 2005 marketing
- 14 plan; right?
- MR. MAIER: Objection. Form.
- 16 A. I really don't know how to answer that
- 17 question. I am not privy to this. I don't remember
- 18 this.
- 19 Q. (By Mr. Faes) Well, was this information
- 20 ever shared with you, that the off-label use for the
- 21 Actiq product in 2005 and 2006 was somewhere between 80
- 22 and 90 percent?
- MR. MAIER: Objection. Form, foundation.
- A. As prior I said, I don't remember.

- 1 Q. (By Mr. Faes) If you had been told that,
- 2 do you think that's something that you would remember?
- MR. MAIER: Objection. Form.
- 4 A. I don't remember it now.
- 5 Q. (By Mr. Faes) Do you have any reason as
- 6 you sit here today to think that those numbers as
- 7 reported in the Wall Street Journal aren't true?
- MR. MAIER: Objection. Foundation.
- 9 A. I think the media is very biased. I do
- 10 not trust things that come out of the media. If you
- 11 show me a double-blind placebo-controlled study I will
- then look at it, but if you're showing me something the
- 13 media generated as -- me as an individual, Val Kaisen,
- 14 I do not believe -- put a lot of weight into it.
- Q. Do you think that the company's marketing
- 16 plan from 2005 is reliable? Do you believe the 90
- 17 percent figure of off-label use from that document?
- 18 MR. MAIER: Objection. Foundation.
- 19 A. If they say it is, then yes.
- 20 O. (By Mr. Faes) So the company document
- 21 estimating 90 percent in your mind is more reliable
- than the Wall Street Journal which only estimates 80
- 23 percent; right?
- MR. MAIER: Objection. Form.

- 1 A. I don't believe the media, period. Do I
- 2 recognize those numbers from the marketing material? I
- don't remember. I'm staying pretty consistent in my
- 4 answers here, so I'm not sure what you -- you want me
- 5 to reiterate it again?
- 6 Q. (By Mr. Faes) No, I think you've answered
- 7 my question.
- 8 A. Thank you.
- 9 [Discussion off the record.]
- MR. FAES: Would you mind if we just went
- off the record just for a minute -- for five minutes?
- 12 THE VIDEOGRAPHER: We are going off the
- 13 record -- going off the record at 1:31 PM.
- [A brief recess was taken.]
- THE VIDEOGRAPHER: We are back on the
- 16 record at 1:56 PM.
- Q. (By Mr. Faes) Ms. Kaisen, we're back on
- 18 the record after a brief lunch break. Are you ready to
- 19 proceed?
- 20 A. Yes.
- Q. Now, all morning we've been talking about
- 22 Actiq --
- UNIDENTIFIED WOMAN: I'm sorry. Can you
- 24 unmute the phone again, please?

- 1 [Discussion off the record.]
- Q. (By Mr. Faes) So Ms. Kaisen, all morning
- 3 we've been talking about your detailing and promotion
- 4 of Actiq; right?
- 5 A. Yes.
- 6 Q. And as we discussed earlier in the day, in
- 7 late 2006, you -- or early 2007, you discontinued your
- 8 promotion and detailing of Actiq and switched to
- 9 promoting Fentora in place of it; right?
- 10 MR. MAIER: Objection. Form.
- 11 A. If you say so yes.
- Q. (By Mr. Faes) Well, you don't dispute
- 13 that that happened?
- 14 A. I don't dispute it.
- 15 Q. You're just not sure of the dates; is that
- 16 right?
- 17 A. Yes. Thank you. Yes.
- 18 Q. So I'm going to hand you what's been
- 19 marked as -- well, I got to mark it first. I'm going
- 20 to hand you what's eventually going to be marked as
- 21 Exhibit Number 15 to your deposition. And I know this
- is a huge document, but I'm only going to ask you
- 23 about -- I know this is a huge document, but I'm only
- 24 going to ask you about four pages from it.

- 1 [Exhibit Teva-Kaisen-015
- 2 marked for identification.]
- Q. And it might even be easier just to --
- 4 that's yours. I always give you yours first, so maybe
- 5 I need to reverse the order on that.
- 6 A. Yeah.
- 7 Q. So this is a document titled FEBT
- 8 2005-2006 marketing plan. Do you see that?
- 9 A. Uh-huh.
- 10 Q. And you knew that FEBT was the
- 11 pre-approval name essentially for what eventually
- 12 became Fentora; right?
- 13 A. I don't remember.
- Q. Okay. Well, I'll represent to you that
- 15 that is the case, that FEBT is what ultimately became
- 16 Fentora and that's what this is, is the 2005 and 2006
- 17 marketing plan. Fair enough?
- 18 A. Yes.
- 19 Q. If you turn to Page 6 of this document and
- 20 if you look up in critical success factors up in the
- 21 upper right-hand corner, it states that a critical
- 22 success factor in launching Fentora was to convert
- 23 Actiq loyalists within 90 days. Do you see that?
- A. Uh-huh.

- 1 Q. Was that one of the directives given to
- 2 you by your superiors when Fentora was launched, was
- 3 that you wanted to convert Actiq loyalists within 90
- 4 days of the launch?
- 5 A. I don't remember.
- 6 Q. Do you have any reason as you sit here
- 7 today to dispute that that was direction given to you
- 8 by your superiors when Fentora was launched?
- 9 A. I don't.
- 10 MR. MAIER: Objection. Foundation.
- 11 Q. (By Mr. Faes) If you can turn to Page 8
- of this document, starting on the third paragraph from
- the bottom, it states in order to create a significant
- 14 adoption of fentanyl effervescent buccal tablet, FEBT,
- 15 Cephalon must take a two-step approach, successfully
- 16 convert Actiq loyalists to FEBT adopters within the
- 17 first 90-day prelaunch period, and expand the universe
- of ROO-prescribing physicians. Do you see that?
- MR. MAIER: Objection. Form.
- 20 A. Yes.
- Q. (By Mr. Faes) And ROO means rapid onset
- 22 opioid; right?
- 23 A. Thank you. Yes.
- Q. And the former attempt will be the

- 1 priority at launch because of the loss of Actiq patent
- 2 protection just prior to or at the launch of FEBT. Do
- 3 you see that?
- 4 A. I see it.
- 5 Q. Is this consistent with your memory of
- 6 what you would have been given direction on regarding
- 7 marketing efforts for the launch of Fentora?
- MR. MAIER: Objection. Form.
- 9 A. Yes.
- 10 Q. (By Mr. Faes) And --
- 11 A. I didn't -- I don't remember the part with
- 12 Actiq patent protection, though.
- Q. Okay. But do you have any reason to
- 14 dispute that?
- 15 A. No.
- 16 Q. That would be normal within the industry
- 17 to stop promoting a branded product once it loses
- 18 patent protection; right?
- 19 A. Yes.
- Q. And you would expect that based on your
- 21 long history --
- 22 A. Yes.
- Q. -- of working in the industry; right?
- A. (Nodding "yes.")

- 1 Q. Is that a yes? You're just shaking your
- 2 head.
- 3 A. Yes.
- 4 Q. Okay. Sorry. I just have to have the
- 5 verbal answer for the record. And the following
- 6 sentence says because of the absence of time to convert
- 7 Actiq loyalists to FEBT adopters, both the market and
- 8 Cephalon must be fully prepared for the FEBT launch.
- 9 Do you see that?
- 10 A. Uh-huh.
- 11 Q. And is that consistent with your memory,
- is that once the Fentora product was ready for launch,
- 13 you guys wanted to be ready right away to get out there
- in the field and start converting doctors to the
- 15 Fentora product?
- 16 A. Yes.
- 17 MR. MAIER: Objection. Form.
- 18 Q. (By Mr. Faes) And if you can turn to Page
- 19 12 of this document. You know what? I think this is
- 20 all repetitive of what I've already asked you, so you
- 21 can set that aside. I'm going to hand you what's been
- 22 marked as Exhibit Number 16 to your deposition.
- 23 [Exhibit Teva-Kaisen-016
- 24 marked for identification.

- 1 MR. FAES: You know what? I should give
- 2 her the copy with the binder clip.
- Q. (By Mr. Faes) This is his. This is
- 4 yours.
- 5 A. Oh.
- 6 O. So Exhibit Number 15 is a document --
- 7 MS. JAIN: 16.
- 8 Q. (By Mr. Faes) -- labeled marketing plan
- 9 2007 for Fentora. Do you see that?
- 10 A. Yes.
- 11 THE VIDEOGRAPHER: Excuse me. Your
- 12 microphone I think fell off again.
- 13 [Discussion off the record.]
- Q. (By Mr. Faes) So Exhibit Number 16 is a
- 15 PowerPoint titled marketing plan 2007 and it's for
- 16 Fentora; right?
- 17 A. Yes.
- 18 Q. And if you turn to Slide 49 of this
- 19 document. And if you want we'll just put it up on the
- 20 screen. You see --
- 21 A. Yeah, I see that.
- Q. -- the title of this slide is Actiq
- 23 monthly prescriber account, and this states that PCPs
- or primary care providers continue to outnumber pain

- 1 specialists. Do you see that?
- 2 A. Yes.
- Q. And according to this document, at least
- 4 at the time of the launch of Fentora in -- at least at
- 5 the time in September 2006, which is when this pie
- 6 graph was prepared, the primary care providers as a
- 7 group outnumbered pain specialists in terms of the
- 8 number of -- in terms of the prescriber account; right?
- 9 MR. MAIER: Objection. Foundation.
- 10 A. Yes.
- 11 Q. (By Mr. Faes) And is that consistent with
- 12 your memory with regard to Actiq in September of 2006?
- 13 A. I really don't remember, but if you say
- 14 so.
- 15 Q. Do you have any reason to dispute that
- 16 this --
- 17 A. No.
- 18 Q. -- isn't true? If you can turn to Page
- 19 51 of this document. Again, this is from a marketing
- 20 plan 2007 for Fentora. States conditions treated with
- 21 Actiq. You see that title?
- 22 A. Yes.
- Q. And it says despite promotion in
- 24 breakthrough cancer pain, Actiq uses -- Actiq use

- 1 mirrors that of all opioids, and if you see on the
- 2 left-hand side there it shows a breakdown of the
- 3 underlying conditions being treated with Actiq at that
- 4 time. Do you see that?
- 5 A. Yes.
- 6 Q. And you see that 38 percent of Actiq use
- 7 is for back pain, 22 percent is for neurology, 14
- 8 percent is for headache, eight percent is for cancer,
- 9 and six percent is for arthritis; right?
- 10 A. Yes.
- 11 Q. And those are all -- except for cancer,
- those are all off-label indications; right?
- MR. MAIER: Objection. Foundation.
- 14 A. Yes.
- Q. (By Mr. Faes) So what this slide is
- 16 saying is despite the way Actiq is being promoted, it
- 17 looks like the majority of prescribers at this time,
- 18 according to the company's data, are using it for
- 19 off-label use; right?
- MR. MAIER: Objection. Form.
- 21 A. Yes.
- 22 Q. (By Mr. Faes) Is that consistent with
- 23 your understanding of Actiq use at this time in late
- 24 2006?

- 1 MR. MAIER: Objection. Foundation.
- 2 A. I don't remember.
- Q. (By Mr. Faes) Do you have any reason to
- 4 believe that this data from this company document isn't
- 5 true?
- 6 A. I don't.
- 7 Q. If you look at Page 67 of this document,
- 8 you see a -- you see a breakdown of Fentora
- 9 productivity by specialty. Do you see that?
- 10 A. Yes.
- 11 Q. And you've got it broken down by pain,
- 12 anesthesiologist, primary care physicians, neurologist,
- 13 physio -- what's --
- MS. JAIN: I think it's psychiatry.
- MR. BERG: Psychiatry.
- 16 A. That's psychiatrist.
- 17 Q. (By Mr. Faes) Right. Psychiatrists,
- 18 oncologists, and all others. Do you see that?
- 19 A. Yes.
- MR. MAIER: Objection. Form.
- Q. (By Mr. Faes) So it appears at this time
- in 2006 there are a large number of people who aren't
- oncologists or pain specialists using Fentora at this
- 24 time, according to this document; right?

- 1 MR. MAIER: Objection. Form.
- 2 A. Yes.
- Q. (By Mr. Faes) And is that consistent with
- 4 your understanding of Fentora use at that time?
- 5 MR. MAIER: Objection. Foundation.
- 6 A. I don't remember at that time.
- 7 Q. (By Mr. Faes) Do you have any reason to
- 8 dispute that the information presented in this company
- 9 document isn't true?
- 10 A. No.
- 11 Q. Let me reask it a better way. Do you have
- 12 any reason to believe that the information presented in
- 13 this company document isn't true?
- 14 A. Having a moment here. Sorry. I don't.
- 0. Okay. You can set that document aside.
- A. Whew.
- 17 Q. I'm going to hand you what's been marked
- 18 as Exhibit Number 17 to your deposition.
- 19 [Exhibit Teva-Kaisen-017
- 20 marked for identification.]
- Q. There's his. There's yours.
- MR. FAES: I have a bonus copy of this one
- 23 if you want it.
- MR. MAIER: I've made it this far.

- 1 MR. FAES: Okay.
- Q. (By Mr. Faes) So this has a placeholder
- on the front of it, but if you turn to the first slide
- 4 it states Ohio area business review and it's dated May
- 5 13th of 2008. Do you see that?
- 6 A. Uh-huh.
- 7 Q. And in 2008 you would have been in the
- 8 Ohio Valley area; right?
- 9 A. Yes.
- 10 Q. And Michael Morreale would have been your
- 11 direct report at this time; right?
- 12 A. Yes.
- 13 Q. The page -- and if you can turn to Page 3
- of this document. You see it's got a layout of various
- 15 territories. And again, your name was McGinley at this
- 16 time; right?
- 17 A. Yes.
- 18 Q. So -- and this is just more of a visual so
- 19 we can see. You'd agree that that red shaded area up
- 20 there would have represented your territory at this
- 21 time in 2008; right?
- 22 A. Yes.
- Q. And that was the territory where you were
- 24 promoting, among other things, Fentora, right, in 2008?

- 1 A. Yes. I'm sorry. I was looking up there,
- 2 Erie. I don't remember that one. But okay. Yes.
- Q. And as we discussed earlier, your
- 4 territory at all times when you were detailing and
- 5 promoting Actiq and Fentora included Cleveland and part
- 6 of Ohio; right?
- 7 A. Yes.
- Q. If you can turn to Page 11 of this
- 9 document, and this is a slide entitled Fentora
- 10 learning, and you see that the last bullet point notes
- 11 that over the six months' script data, 60 percent of
- the area scripts are for 200 and 400 MCGs, while only
- 13 25 percent are for 600 and 800 MCGs. Do you see that?
- 14 A. Yes.
- Q. Do you remember at this time in 2008 that
- the lower doses of Fentora, which would be the 200 and
- 17 400 MCGs, were a higher percentage of the
- 18 prescriptions?
- 19 A. Yes.
- 20 MR. MAIER: Objection. Foundation.
- Q. (By Mr. Faes) Did you come to learn as a
- 22 sales representative that the price point for the
- 23 higher doses at 600 or 800 MCGs cost more?
- 24 A. Yes.

- 1 Q. And so it would be true then that if
- 2 physicians prescribed the higher doses for Fentora or
- 3 started a person on a higher dose, that would mean more
- 4 revenue for the company; right?
- 5 MR. MAIER: Objection. Form, foundation.
- 6 A. Could you ask that question again?
- 7 Because they wouldn't start on a higher dose --
- 8 Q. (By Mr. Faes) Sure. It would be true
- 9 then that if physicians prescribed their patients a
- 10 higher dose for Fentora, that would mean more revenue
- 11 for their company; right?
- 12 A. Yes.
- MR. MAIER: Objection. Form, foundation.
- Q. (By Mr. Faes) Oh, you answered it. I
- 15 didn't realize it. I'm sorry. I didn't hear the -- I
- 16 thought you were looking through --
- 17 A. I'm just reading along waiting for you to
- 18 ask a question.
- 19 Q. I thought you were looking through the
- thing and trying to come up with an answer.
- 21 A. No.
- Q. I didn't see that you'd answered yes, so I
- 23 apologize. So if you turn to the next page of this
- 24 document, which is Slide 12. You see that this slide

- 1 is titled keys to success for Fentora, and you see that
- 2 the bottom bullet point is educate physicians about the
- 3 benefits of proper utilization of Fentora via increase
- 4 in number of units per script and strength? Do you see
- 5 that?
- 6 A. Yes.
- 7 Q. So that was something that your superiors,
- 8 including your direct report, Michael Morreale,
- 9 believed was important for a sales rep to do, was to
- 10 talk to physicians about increasing the number of units
- 11 per script in strength?
- MR. MAIER: Objection. Foundation.
- 13 A. Yes.
- Q. (By Mr. Faes) And so if you go back to
- 15 the bullet point just two points above that. This is
- 16 going to kind of transition to our next topic. One of
- 17 the key success factors that Mr. Morreale, who's your
- 18 direct boss, identified as a key to success for Fentora
- 19 was effective utilization of CSPs; right?
- 20 A. Yes.
- Q. And that means Cephalon speaker programs;
- 22 right?
- 23 A. Yes.
- Q. And we talked about speaker programs

- 1 earlier and I think we used a different acronym when it
- 2 was used for Actiq and now I can't remember what it
- 3 was.
- 4 A. I'm not good at acronyms. Don't ask.
- 5 Q. But they changed the name to Cephalon
- 6 speaker programs; right?
- 7 A. Yes.
- Q. And that's essentially the same as the
- 9 speaker programs that were being done previously with
- 10 Actiq; right?
- 11 A. Yes.
- 12 Q. So -- you can set that document aside. So
- one of your jobs as a sales representative detailing
- 14 Fentora and also earlier Actiq, as we discussed, was to
- 15 set up Cephalon speaker programs for events for
- 16 Fentora?
- 17 A. Yes.
- 18 Q. And what would be some of the qualities
- 19 you would look for as a speaker when looking for a
- 20 Fentora speaker?
- 21 A. Actually, in my territory it would be
- 22 academic speakers, because it's an academic area. I'm
- 23 not going to bring -- I needed high-profile academic
- 24 physicians.

- 1 Q. So one of the qualities would you -- you
- 2 would look for is you want an academic; right?
- 3 A. Uh-huh.
- 4 Q. You would want ideally somebody who was
- 5 high profile; right?
- 6 A. Yes.
- 7 O. And that would mean someone who's
- 8 respected in the community?
- 9 A. Yes, or United States.
- 10 Q. Oh, okay. So you would sometimes bring in
- 11 people from outside of your territory to come in and
- 12 peak to doctors within your territory about Fentora;
- 13 right?
- 14 A. Yes.
- Q. And at this time in -- at the time -- by
- 16 the time you were promoting Fentora starting in late
- 17 2006 or 2007, was there actually an approved list of
- 18 speakers provided by the company?
- 19 A. I don't remember.
- Q. Would you agree with me that regardless of
- 21 whether or not there was a approved list of speakers
- 22 that you ultimately ran any speaker by -- that you
- 23 ulti -- strike that. Would you agree with me that
- 24 regardless of whether there was a list of approved

- 1 speakers, any speaker that you were considering, you
- 2 would ultimately run that name by your superiors before
- 3 you would be given a green light to use that speaker in
- 4 your territory?
- 5 A. Yes.
- 6 MR. MAIER: Objection. Form.
- 7 Q. (By Mr. Faes) So in other words, it
- 8 wasn't 100 percent your decision about whether or not
- 9 to use a particular speaker for Fentora or Actiq;
- 10 right?
- 11 A. Yes.
- 12 Q. You were required by company policy and
- 13 training to check with your superiors to make sure that
- 14 that person was okay before you used that person;
- 15 right?
- MR. MAIER: Objection. Form.
- 17 A. Yes.
- 18 Q. (By Mr. Faes) So I'm going to hand you
- 19 what's been marked as Exhibit Number 18 to your
- 20 deposition.
- 21 [Exhibit Teva-Kaisen-018
- 22 marked for identification.]
- Q. And this is an e-mail -- this is an e-mail
- 24 dated February 19th of 2005. Do you see that?

- 1 A. Yes.
- Q. And this is an e-mail to you -- I'm sorry.
- This is -- starting over. This is an e-mail from
- 4 you --
- 5 A. Uh-huh.
- 6 Q. -- to your boss at this time, Michael
- 7 Morreale, dated February 19th, 2005. Do you see that?
- 8 A. I do.
- 9 MR. BERG: 2015. 2015.
- 10 Q. (By Mr. Faes) So this is an e-mail from
- 11 you to your boss, Michael Morreale, dated February 19th
- 12 of 2005; right?
- 13 A. No, 2015.
- 14 Q. Two -- I did it again. At least I haven't
- 15 talked about Dr. Fentora yet today. So this is an
- 16 e-mail from you to your boss, Michael Morreale, dated
- 17 February 19th, 2015; right?
- 18 A. Yes.
- 19 Q. And you state Michael -- well, actually,
- let's go down to the first part of this e-mail where
- 21 it's from Katie O'Connor, and it states thank you for
- 22 your continued support of the Fentora hcpConnect
- videoconference series. We are hoping to increase the
- 24 number of speakers who can conduct hcpConnect programs

- 1 and we are asking for your assistance. Do you see
- 2 that?
- 3 A. I do.
- 4 Q. And the Fentora hcpConnect videoconference
- 5 series was a -- it was a Cephalon speaker program but
- 6 it was done by videoconference; right?
- 7 A. Yes.
- Q. And it goes on to say we would like each
- 9 regional manager to recommend up to five speakers. Do
- 10 you see that?
- 11 A. Yes.
- 12 Q. And in response to this up above you state
- 13 Michael, in response to speakers, I would like to
- 14 nominate Dr. Riad Laham, Cleveland Clinic Pain
- 15 Management, 6803 Mayfield Road, Maryland Heights (sic),
- 16 Ohio. Do you see that?
- 17 A. Yes.
- 18 Q. So you actually nominated Dr. Laham as a
- 19 potential Fentora speaker?
- 20 A. Yes.
- Q. And he was ultimately approved and you
- 22 used him in speaking events; right?
- 23 A. Yes.
- Q. And if you can -- well, I'm going to set

- 1 that aside. We might come back to that in a minute,
- 2 but -- can you tell me the exhibit number on that?
- 3 MS. JAIN: 18.
- 4 Q. (By Mr. Faes) 18? Thank you. So this is
- 5 a document that I will mark as Exhibit Number 19.
- 6 [Exhibit Teva-Kaisen-019
- 7 marked for identification.]
- 8 Q. And this is a document labeled GTE Actiq
- 9 RMP initial off-label prescriber listing dated July of
- 10 2008. Do you see that?
- 11 A. I do, but it's GPE, and I don't know what
- 12 that stands for.
- Q. Okay. But this -- what it appears to be
- 14 is a list of providers that have prescribed Actiq
- off-label in the past; right?
- MR. MAIER: Objection. Foundation.
- 17 A. Yes.
- 18 Q. (By Mr. Faes) And if you turn to the
- 19 second page of this document, and do you see the second
- 20 column that Dr. Riad Laham is listed on this document
- 21 as a doctor who has prescribed Actiq off-label in the
- 22 past? Right?
- 23 A. Yes.
- O. So it would be true then that in

- 1 accordance with guidance you got from the company, the
- 2 company's knowledge that a physician had prescribed
- 3 either Actiq or Fentora off-label in the past would not
- 4 necessarily disqualify that physician for being a
- 5 potential speaker for those two products; right?
- A. I don't have an answer to that. I wasn't
- 7 privy to that decision.
- 8 Q. So your answer is that you don't know, you
- 9 weren't privy to that decision? Is that accurate?
- 10 A. I nominate, they decide.
- 11 Q. So you would agree with me then that if
- 12 anyone at the company had ever told you that you
- 13 shouldn't nominate or use a speaker for Actiq or
- 14 Fentora if you knew that that person had prescribed
- off-label in the past, you would have followed that
- 16 directive from your superiors; right?
- MR. MAIER: Objection. Form.
- 18 A. Yes.
- 19 Q. (By Mr. Faes) And we can agree that
- 20 Dr. -- since Dr. Laham was ultimately approved by your
- 21 superiors to be a Fentora speaker and they had this
- data, they must have been okay with the fact that he
- 23 had prescribed Actiq off-label in the past --
- MR. MAIER: Objection.

- Q. (By Mr. Faes) -- and that that didn't
- 2 disqualify him from being a potential Fentora speaker;
- 3 right?
- 4 MR. MAIER: Objection. Form, foundation.
- 5 A. Yes.
- 6 O. (By Mr. Faes) Can I have you look back at
- 7 the previous exhibit, which was Exhibit Number 18? So
- 8 if you look at the second page of this document, it
- 9 starts at the top. It says for your reference, the
- 10 list of current hcpConnect speakers is below. Do you
- 11 see that?
- 12 A. Uh-huh.
- Q. And if you look about in the middle of the
- 14 page, you see a Dr. Steve Simon from Leawood, Kansas;
- 15 right?
- 16 A. Yes.
- Q. So at this time in 2015, Dr. Simon was
- 18 already an approved speaker for Fentora by the company;
- 19 right?
- 20 A. Yes.
- Q. And you actually used Dr. Steve Simon in
- 22 your territory to give speaker programs throughout the
- years for both Fentora and Actiq; right?
- 24 A. Yes.

- 1 Q. And you were aware that -- were you aware
- 2 that Dr. Steven Simon had actually been a --
- A. Can we strike that? I don't remember on
- 4 Actiq or Fentora. I remember I used him, but I'm not
- 5 sure which product or both. I'm not sure. But I did
- 6 use him, yes.
- 7 Q. But you know he was an approved speaker
- 8 for both Actiq and Fentora; right?
- 9 A. Yes.
- 10 MR. MAIER: Objection. Form.
- 11 Q. (By Mr. Faes) And you know he gave
- 12 speaker programs throughout the company -- or strike
- 13 that. You know that he gave speaker programs for both
- 14 Actiq and Fentora throughout various parts in the
- 15 United States for the company; right?
- 16 A. Yes.
- 17 MR. MAIER: Objection. Foundation.
- 18 Q. (By Mr. Faes) And you're not saying that
- 19 you didn't use Steven Simon in your territory? You're
- just saying you can't remember one way or the other as
- 21 you sit here today; right?
- 22 A. I did use him in my territory. I just
- 23 can't remember if it was Fentora or Actiq or both.
- Q. (By Mr. Faes) Okay. So what you're

- 1 saying is you might have used him for Actiq -- strike
- 2 that. You might have used him for Actiq or Fentora or
- 3 both? You just can't remember one way or the other as
- 4 you sit here today what you used him for; right?
- 5 A. Yes. Right.
- 6 Q. So I'm going to hand you what's been
- 7 marked as Exhibit Number 20 to your deposition.
- 8 [Exhibit Teva-Kaisen-020
- 9 marked for identification.]
- 10 Q. Sorry. That's his. That's yours. So
- 11 many pieces of paper floating around. So Exhibit
- 12 twenty --
- 13 A. I already saw that.
- Q. So Exhibit Number 20 is an e-mail from
- 15 Philip Tocco to you.
- 16 A. Uh-huh.
- 17 Q. And a Frank Mazzucco dated September 19th
- 18 of 2006; right?
- 19 A. Yes.
- Q. And the subject line is opportunity;
- 21 right?
- 22 A. Yes.
- Q. And this is an e-mail that would have been
- 24 received by you; right?

- 1 A. Yes.
- Q. And it states, hey, team. I wanted to
- 3 share a great and rare opportunity with you. Dr. Simon
- 4 will be able to conduct Fentora programs made during
- 5 the Fentora launch. As you know, Dr. Simon is
- 6 currently capped at the current time. An exception has
- 7 been made for the remainder of the year pending the
- 8 approval of Fentora. Dr. Simon will be available for
- 9 an extra 25K in talks beginning at launch and ending
- 10 December 31st. After this date, his total cap will
- 11 return to 100K as before. Do you see that?
- 12 A. Yes.
- Q. So this reflects that someone at the
- 14 company is sending you an e-mail indicating that Dr.
- 15 Simon is a approved speaker that you might want to
- 16 consider to give talks about the Fentora product which
- is about to launch at this time; right?
- 18 A. Yes.
- MR. MAIER: Objection. Form, foundation.
- 0. (By Mr. Faes) And this indicates that he
- 21 generally has a cap of \$100,000 a year. Is that your
- 22 understanding from reading this?
- MR. MAIER: Objection. Foundation.
- 24 A. Yes.

- Q. (By Mr. Faes) And it appears that he --
- 2 did you understand -- strike that. Did you understand
- 3 when you worked at Cephalon that the company generally
- 4 had a policy not to pay speakers for any product more
- 5 than \$100,000 in a single year?
- 6 A. Yes.
- 7 Q. And it looks like they're making an
- 8 exception in this case because Dr. Simon is close to
- 9 that \$100,000 cap, so they're approving him for an
- 10 extra \$25,000 for the -- through the end of the year
- 11 for the launch of Fentora; right?
- MR. MAIER: Objection. Foundation.
- 13 A. Yes.
- 14 Q. (By Mr. Faes) So that would indicate that
- 15 he had actually done quite a few speaker programs for
- 16 Cephalon at this time if he's already at or approaching
- 17 his \$100,000 cap; right?
- 18 MR. MAIER: Objection. Form.
- 19 A. If you say so.
- Q. (By Mr. Faes) And if you go to the final
- 21 sentence, this states that since time and money may be
- 22 limited during the launch, I can say that Dr. Simon is
- 23 quite good at conducting teleconferences, so that might
- 24 be a great way of maximizing the use of Dr. Simon. Do

- 1 you see that?
- 2 A. I do.
- 3 Q. So this is direction from Mr. Philip Tocco
- 4 at the company essentially endorsing Dr. Simon as a
- 5 person who's good for conducting teleconferences on the
- 6 Fentora product; right?
- 7 MR. MAIER: Objection. Form.
- 8 A. Yes.
- 9 Q. (By Mr. Faes) And he's recommending that
- 10 you strongly consider using Dr. Simon for Fentora
- 11 speaking programs in your territory or he wouldn't have
- 12 sent it to you; right?
- MR. MAIER: Objection. Form, foundation.
- 14 A. He's just saying FYI. David Hennecke is
- the one that's saying it's a good opportunity.
- Q. (By Mr. Faes) But that's the message that
- 17 you would have received from the company upon getting
- 18 this e-mail --
- 19 A. Yes.
- 20 O. -- is that the company thought it was a
- 21 good idea to use Dr. Simon for tele -- for a
- teleconference to do a speaker program for the Fentora
- 23 launch; right?
- MR. MAIER: Objection. Form, foundation.

- 1 A. Yes. I just wanted to qualify that you
- 2 said that Phil Tocco had said that was a great and rare
- 3 opportunity when it was really David Hennecke.
- Q. (By Mr. Faes) Right. He just forwarded
- 5 it --
- 6 A. Yes.
- 7 Q. -- and it was David Hennecke that sent
- 8 the initial e-mail; right?
- 9 A. Yes.
- 10 Q. Who was David Hennecke?
- 11 A. I don't know what he was at that time.
- 12 Manager or -- maybe manager or -- I forget what they
- 13 call them. Managed care person. I'm not sure. I
- don't remember.
- 15 Q. So during your time using Dr. Simon as a
- 16 speaker for products within your territory, did you
- 17 come to learn that prior to becoming a medical doctor,
- 18 he had actually been a pharmacist?
- 19 A. I did not know that.
- 20 Q. And did you know that prior to becoming a
- 21 pharmacist -- strike that. Did you know that prior to
- 22 becoming a doctor when he was a pharmacist in Kansas
- 23 City, he actually pled guilty to a felony of
- 24 intentionally distributing controlled substances?

- 1 A. No idea.
- Q. I'm going to hand you what's been marked
- 3 as Exhibit Number 21 to your deposition.
- 4 [Exhibit Teva-Kaisen-021
- 5 marked for identification.]
- 6 Q. And as you can see from the top, this is a
- 7 document --
- 8 A. Wow.
- 9 Q. -- that indicates it's the State Board of
- 10 Pharmacy versus Steve Simon and it's got a stamp of
- 11 November 6th of 1975 at the top. Do you see that?
- 12 A. Okay. Yeah.
- Q. And the complaint states that -- well, and
- it's versus Steve Simon, who's from Kansas City; right?
- 15 A. Right.
- Q. And it's the -- Number 3 of the complaint
- 17 states that the respondent was found guilty in the
- 18 United States District Court for the Western District
- of Missouri on December 8th, 1975, of the offense of --
- 20 A. Wow.
- Q. -- knowingly and intentionally
- 22 distributing controlled substances; right?
- A. Wow. Wow.
- Q. And if you turn -- well, strike that.

- 1 So -- and if you see the -- at the bottom of the page,
- of the same page, it notes that the State Board of
- 3 Pharmacy has determined that the conviction constitutes
- 4 unprofessional conduct under the provisions of Section
- 5 338.055, RSMo 1969, which provides in part the
- 6 following specifications shall be deemed unprofessional
- 7 or dishonorable conduct within the meaning of this
- 8 section. Conviction of a felony. Do you see that?
- 9 A. Yeah.
- 10 Q. So apparently Dr. Steve Simon is a
- 11 convicted felon; right?
- 12 A. Wow.
- MR. MAIER: Objection. Foundation. Form.
- 14 A. Yes.
- O. (By Mr. Faes) And we saw from documents
- we looked at earlier that as early as 2006, the
- 17 company -- people at the company were recommending that
- 18 you use him as a potential speaker in your territory;
- 19 right? He was on an approved list provided by the
- 20 company; right?
- 21 A. Yes.
- MR. MAIER: Objection. Form.
- Q. (By Mr. Faes) And you had an expectation
- that if the company was sending you around an approved

- 1 list of speakers, the company would have done their due
- diligence in making sure that those people were
- 3 appropriate speakers for the promotion of Fentora;
- 4 right?
- 5 A. Yes.
- 6 Q. And you would never expect that the
- 7 company would put somebody on that list who was a
- 8 convicted felon; right?
- 9 MR. MAIER: Objection. Form.
- 10 A. Are you asking me right or yes or no? I
- 11 would never have expected the company. So rephrase
- 12 your question. The --
- Q. (By Mr. Faes) You never -- my question
- 14 is, you never expected that the company would put
- 15 someone on the approved speaker list who was a
- 16 convicted felon; right?
- MR. MAIER: Objection. Form.
- 18 A. True.
- 19 Q. (By Mr. Faes) And certainly not one who
- 20 was convicted of intentionally distributing controlled
- 21 substances; right?
- 22 A. True.
- MR. MAIER: Objection. Form.
- Q. (By Mr. Faes) Which is the very type of

- 1 product that Fentora and Actiq is; right?
- 2 A. Yes.
- MR. MAIER: Objection. Form.
- 4 Q. (By Mr. Faes) They're both controlled
- 5 substances? If someone at the company had told you
- 6 that, you certainly wouldn't have used him as a speaker
- 7 in your territory; right?
- 8 A. Never.
- 9 MR. MAIER: Objection. Form.
- 10 Q. (By Mr. Faes) And you relied on the
- 11 company to check that out for you? You understood that
- there were other people in the company who were
- 13 supposed to vet and make sure that the people that went
- on that list were appropriate; right?
- 15 A. Yes.
- Q. Do you feel duped that the company
- 17 provided you a list that had a convicted felon who pled
- 18 guilty to intentionally distributing controlled
- 19 substances on that list?
- MR. MAIER: Objection. Form.
- 21 A. I don't like the word duped, but I don't
- 22 like it. Wow.
- Q. (By Mr. Faes) Now, remember -- hold on
- just a sec. Now, remember we were looking back earlier

- 1 in the day at a list of speakers that -- speaker
- 2 programs that you conducted in your territory in 2002;
- 3 right?
- 4 A. Yes.
- 5 Q. And one of the speakers that you used I
- 6 think at least three times was a Dr. James Bressi?
- 7 A. Yes.
- 8 Q. You did use him three times; right?
- 9 A. Okay.
- 10 Q. You can look back at the exhibit if you
- 11 need to, but --
- 12 A. If you say so, yes.
- Q. Do you want to look at the exhibit again,
- 14 or --
- 15 A. No.
- 16 Q. So you used Dr. Bressi at least three
- times to promote Actiq in your territory in 2002;
- 18 right?
- 19 A. Yes.
- Q. Do you recall how many times you did use
- 21 him?
- 22 A. No.
- Q. I'm going to hand you what's been marked
- 24 as Exhibit Number 22 to your deposition.

- 1 [Exhibit Teva-Kaisen-022
- 2 marked for identification.]
- Q. There you go. And this is a document from
- 4 the Akron Beacon Journal, ohio.com. Do you see that?
- 5 A. I do.
- 6 Q. And the headlight is Stow pain clinic
- 7 closing after court upholds sexual imposition
- 8 conviction against doctor accused of abusing patients.
- 9 Do you see that?
- 10 A. I do.
- 11 Q. And it says Summit Pain Specialists in
- 12 Stow is permanently closing Monday after years of
- wrangling over a sex abuse scandal involving a doctor
- 14 there. Do you see that?
- 15 A. I do.
- 16 Q. And it says in the second paragraph the
- 17 Ohio Supreme Court on August 3rd upheld the Summit
- 18 County Common Pleas Court conviction of former doctor
- 19 James Bressi, who once co-owned the business doctor --
- 20 with former doctor Robert Stephen Geiger. Do you see
- 21 that?
- 22 A. Yes.
- Q. And that appears to be the same Dr. James
- 24 Bressi that you used as a speaker for Actiq at one

- 1 point; right?
- 2 A. Yes.
- Q. And it goes on to state that the clinic's
- 4 troubles started in 2001, when patients began calling
- 5 the Stow police reporting that they had been sexually
- 6 abused by Bressi inside the pain clinic. Do you see
- 7 that?
- 8 A. You said 2001.
- 9 Q. Huh?
- 10 A. You mean 2012?
- 11 Q. Yes, I do. And it states that the
- 12 clinic's trouble started in 2012, when patients began
- 13 calling Stow police reporting that they had been
- 14 sexually abused by Bressi inside the pain clinic;
- 15 right?
- 16 A. I see it.
- Q. Did you ever see anything unusual or out
- of the ordinary when you called on Dr. Bressi's office?
- MR. MAIER: Objection. Form.
- 20 A. No.
- Q. (By Mr. Faes) And you certainly would
- 22 have never used Dr. Bressi if you thought he was the
- 23 type of doctor -- strike that. You certainly would
- 24 have never used Dr. Bressi as a Cephalon speaker if you

- 1 had known that he was sexually abusing patients inside
- 2 his office; right?
- MR. MAIER: Objection. Form.
- 4 A. This was 2016. When I used him it was
- 5 prior to this.
- 6 Q. (By Mr. Faes) Right. And you never would
- 7 have used him if you knew anything like that was going
- 8 on; right?
- 9 MR. MAIER: Objection. Form.
- 10 A. True. It's a different time period.
- 11 Q. (By Mr. Faes) So you can set that
- document aside. Now, during your time as a rep for
- 13 Cephalon detailing Actiq and Fentora, you would have
- 14 called on a Dr. -- would you have called on a Dr.
- 15 Gregory Gerber?
- 16 A. Yes.
- Q. G-E-R-B-E-R. What do you remember about
- 18 Dr. Gerber?
- 19 A. Pain management out in Sandusky, married
- 20 to a pharmacist, and had a special needs daughter.
- Q. What do you remember about the nature of
- 22 his practice?
- 23 A. Pain management.
- Q. So he was a pain management doctor?

- 1 A. Uh-huh.
- Q. What do you remember about the kinds of
- 3 patients that he saw?
- 4 MR. MAIER: Objection. Form.
- 5 A. Pain management patients.
- 6 O. (By Mr. Faes) Do you remember seeing
- 7 anything unusual or out of the ordinary when you
- 8 visited Dr. Gerber's office?
- 9 A. No.
- 10 MR. MAIER: Objection. Form.
- 11 Q. (By Mr. Faes) Do you remember anything
- 12 you ever saw in Dr. Gerber's office that would cause
- 13 you to suspect there were any diversion of opioids
- 14 taking place?
- MR. MAIER: Objection. Form.
- 16 A. No.
- Q. (By Mr. Faes) And you would have called
- on Gerber a number of times; right?
- 19 A. Off and on for the years.
- 20 Q. And he would have been one of the top
- 21 prescribers in your territory at one time; right?
- MR. MAIER: Objection. Form.
- 23 A. For --
- Q. (By Mr. Faes) For Fentora.

- 1 MR. MAIER: Same objection.
- 2 A. I don't remember if he was one of the top
- or the top or whatever while I was detailing him.
- Q. (By Mr. Faes) Okay. Well, I'm going to
- 5 hand you what's been marked as Exhibit Number 23 to
- 6 your deposi -- that's my copy. I'm going to hand you
- 7 what's been marked as Exhibit Number 23 to your
- 8 deposition.
- 9 [Exhibit Teva-Kaisen-023
- 10 marked for identification.]
- MR. FAES: And this is 22 for you, Mike.
- 12 A. Okay.
- 13 Q. (By Mr. Faes) And these are your call
- 14 notes or call log.
- A. Uh-huh.
- Q. Whichever you prefer. Would you call
- these your call notes or call logs?
- 18 A. They're not notes, so I guess they would
- 19 be logs.
- Q. So these are your call logs to Dr. Gregory
- 21 Gerber --
- A. Uh-huh.
- Q. -- from July 18th of 2007 to November
- 24 28th of 2016. Do you see that? Take your time.

- 1 A. Thank you. 12. 12. What? 12. What?
- 2 Yeah, but I didn't have him the whole time. 13. 14.
- Q. Sure. And actually, if you look on the
- 4 first page, it looks like there's a gap between
- 5 December 5th of 2008 and July 14th of 2011. Do you see
- 6 that?
- 7 A. I do. Thank you.
- 8 Q. And that's because during that time he
- 9 wasn't your responsibility; right?
- 10 A. Yes.
- 11 Q. He was assigned to another sales
- 12 representative. I think her name was Nicole Reese.
- 13 Does that sound right?
- 14 A. Yes.
- Q. At any rate, you can count these up if you
- 16 want to, but I count that you made 76 calls to his
- office in this time frame between July 18th of 2007 and
- 18 November 28th of 2016. Do you have any reason to
- 19 dispute that?
- 20 A. No.
- 21 Q. I'm going to hand you what's been marked
- 22 as Exhibit Number 24 to your deposition.
- 23 [Exhibit Teva-Kaisen-024
- 24 marked for identification.

- 1 MR. FAES: I think this is 22.5 for you,
- 2 Mike.
- Q. (By Mr. Faes) So this is an e-mail and
- 4 attachment from Michael Morreale to you and others
- 5 dated June 5th of 2012. Do you see that?
- 6 A. Yeah.
- 7 Q. So this would have been an e-mail that you
- 8 would have received; right?
- 9 A. Yes.
- 10 Q. And it says a list -- here is a list of
- 11 physicians sorted by the stop Subsys writers based on
- 12 the last 26-week period. I also included Fentora and
- 13 Abstral and plan on sending another report sorted by
- 14 the top Abstral writers. Let's make sure we are
- 15 following up with these physicians to remind them why
- 16 Fentora is the best TIRF on the market. Do you see
- 17 that?
- 18 A. Yes.
- 19 Q. And these other products -- Subsys and
- 20 Abstral -- those would be other rapid onset fentanyl
- 21 products that would be kind of competitors to Fentora;
- 22 right?
- 23 A. Yes.
- Q. And this would have been in June of 2012

- 1 while you would have been responsible for calling on
- 2 Dr. Gerber; right?
- 3 A. Okay.
- 4 Q. And in fact, if you want to look back at
- 5 your call notes, you've got three calls in May of 2012
- 6 and two in June of 2012 to Dr. Gerber; right?
- 7 A. Okay. June. June. June 2012. Yes.
- Q. And so if you can turn to the last page of
- 9 this document.
- 10 A. This one?
- 11 Q. Yes, the Exhibit Number --
- 12 A. Okay.
- Q. What exhibit is that?
- MR. BERG: 24.
- 15 A. Thank you.
- 16 Q. (By Mr. Faes) If you can turn to the last
- 17 page of Exhibit Number 24 for me.
- 18 A. Yeah.
- 19 Q. And you can see actually the very first
- 20 line of this is sales rep name Valerie Kaisen, Gerber,
- 21 Gregory, and it looks like his weekly product TRx
- 22 total, which would be prescription total at this time,
- 23 was 41; right?
- A. Wow. Yeah.

- 1 O. So that would indicate that he was one of
- 2 the higher prescribers of Fentora at this time; right?
- 3 A. Yes.
- 4 MR. MAIER: Objection. Form, foundation.
- 5 Q. (By Mr. Faes) And you'd agree with me
- 6 that you wouldn't be looking -- it wouldn't be your
- 7 job -- it wouldn't be your job to look at this report
- 8 or any other report for signs that a prescriber's
- 9 orders were suspicious; right?
- MR. MAIER: Objection. Form.
- 11 A. Right.
- 12 Q. (By Mr. Faes) That would be someone
- 13 else's job at the company; right?
- 14 A. Right.
- Q. And you would be relying on others at the
- 16 company for that; right?
- 17 A. Repeat your question. I'm sorry. I'm
- 18 getting a little --
- 19 Q. You would be relying on others at the
- 20 company to look at reports of prescriptions or sales or
- 21 distribution for signs that a prescriber's orders were
- 22 suspicious; right?
- 23 A. Yes.
- MR. MAIER: Objection. Form.

- 1 Q. (By Mr. Faes) That was somebody else's
- 2 responsibility; right?
- 3 A. Yes.
- 4 Q. And you relied on other people at the
- 5 company to make sure that that was getting done; right?
- 6 MR. MAIER: Objection. Form.
- 7 A. Yes.
- 8 Q. (By Mr. Faes) And if someone told you
- 9 that has a prescriber's orders were suspicious or
- 10 indicative of potential diversion, you wouldn't call on
- 11 that physician anymore; right?
- 12 A. Yes.
- MR. MAIER: Objection. Form.
- Q. (By Mr. Faes) And nobody ever told you
- 15 that with regard to Dr. Gerber; right?
- 16 A. No.
- 17 Q. I'm going to hand you what's been marked
- 18 as Exhibit Number 25 to your deposition.
- 19 [Exhibit Teva-Kaisen-025
- 20 marked for identification.]
- 21 Q. That's yours. You gave him the wrong copy
- 22 again. So this is a press release from the Department
- of Justice dated August 22nd of 2018. Do you see that?
- 24 A. Yeah. I'm seeing -- yeah.

- 1 Q. And the headline is Justice Department
- 2 takes first-of-its-kind legal action to reduce opioid
- 3 over-prescription. Do you see that?
- 4 A. Yes.
- 5 Q. And it states the Justice Department has
- 6 filed a complaint to bar two Ohio doctors from
- 7 prescribing medications after an investigation revealed
- 8 that they recklessly and unnecessarily distributed
- 9 painkillers and other drugs. Temporary restraining
- orders, a first of its kind against doctors allegedly
- 11 prescribing opioids under the Controlled Substances
- 12 Act, were served this week that prevent -- that forbid
- 13 Michael P. Tricaso, D.O., of Akron, and Gregory J.
- 14 Gerber, M.D., of Sandusky from writing prescriptions.
- 15 Do you see that?
- 16 A. I do.
- 17 Q. Were you aware that the Department of
- 18 Justice filed a complaint and got a temporary
- 19 restraining order preventing Dr. Gerber from writing
- 20 prescriptions in 2018?
- 21 A. No.
- Q. If you go down to the second-to-last
- 23 paragraph, the press release states these doctors were
- 24 simply drug dealers in white lab coats, said U.S.

- 1 Attorney Justin Herdman. They illegally prescribed
- 2 painkillers and other drugs for no legitimate medical
- 3 purpose. Putting so-called physicians like these out
- 4 of business is one of several steps we are taking to
- 5 turn the tide on opioid and drug crisis that has caused
- 6 so much death and heartbreak in our community. Do you
- 7 see that?
- 8 A. I do.
- 9 Q. After having read this and becoming aware
- of this, do you wish someone at Teva had found -- had
- 11 reviewed Dr. Gerber's reports of ordering and Fentora
- 12 and if they found it to be suspicious reported that to
- 13 you?
- MR. MAIER: Objection. Form, foundation.
- 15 A. I wasn't here at the time, but if there
- 16 was anything suspicious, yes. I was not working at the
- 17 company at this time.
- 18 Q. (By Mr. Faes) If you turn to the second
- 19 page of this. It states that Gerber in October of 2017
- 20 began seeing an undercover federal agent. The
- 21 undercover agent did not complain of pain during each
- of their six visits and Gerber received a minimal
- 23 medical examination, but each time Gerber prescribed
- 24 controlled substances for the undercover agent,

- 1 including oxycodone, dronabinol, and alprazolam. Do
- 2 you see that?
- 3 A. I do.
- 4 Q. You'd agree with me that you wouldn't want
- 5 to call on a doctor that would knowingly prescribe a
- 6 opioid narcotic to someone who didn't have an
- 7 underlying necessary medical condition with a minimal
- 8 medical examination; right?
- 9 MR. MAIER: Objection. Form, foundation.
- 10 A. I would want to know -- your question
- 11 needs to be a little more directed. I would not -- I
- 12 would want to know. There's several parts to your
- 13 question.
- Q. (By Mr. Faes) You're right. It's a bad
- 15 question. Let me try to ask a better one. You'd agree
- 16 with me that you wouldn't want to call on a doctor
- who's illegally prescribing a narcotic to a person who
- 18 doesn't need it; right?
- 19 A. Yes.
- 20 O. And I understand that this event that's
- 21 being reported in here was in October of 2017, but you
- last called on Dr. Gerber on November 28th of 2016;
- 23 right?
- A. Okay. Yes.

- 1 Q. And if you look in the paragraph above
- 2 this, it looks like some of Dr. Gerber's conduct
- 3 occurred during the time that you called on him between
- 4 2013 and 2016. States Dr. Gerber operated Gregory
- 5 Gerber, M.D., LLC, from 2819 Hayes Avenue, Suite 4,
- 6 Sandusky. Gerber received \$175,000 between 2013 and
- 7 2016 from Insys Therapeutics, Inc., to promote Subsys,
- 8 a liquid formulation of fentanyl applied under the
- 9 tongue, a spray used to treat cancer-related pain. Do
- 10 you see that?
- 11 A. I do.
- 12 Q. And that was a product that he was also
- 13 prescribing according to the exhibit we looked at where
- 14 he was prescribing 41 Fentora prescriptions a week;
- 15 right? He was also prescribing 13 -- writing 2013
- 16 Subsys prescriptions at that time a week; right?
- MR. MAIER: Objection. Form, foundation.
- 18 A. Okay.
- 19 Q. (By Mr. Faes) And so if we look back at
- 20 Exhibit Number 23, which are your call notes to Dr.
- 21 Gerber. Call log to Dr. Gerber.
- MR. FAES: I think it's 22 for you, Mike.
- Q. (By Mr. Faes) You noticed that on this
- 24 particular document, you didn't have the discretion to

- 1 put in any call comments at this time like you were
- 2 able to prior to 2006 with the other call notes that we
- 3 looked at earlier today; right?
- 4 A. Yes.
- 5 MR. FAES: And can we put up Exhibit 3 and
- 6 Exhibit 23 up side-by-side, which I think is that one
- 7 and 7.1, Mike?
- 8 Q. (By Mr. Faes) So if we look at Exhibit
- 9 Number 3 on the left, you can see that at that time
- 10 prior to 2006 you had the ability to put in call
- 11 comments detailing at least some of what occurred
- 12 during your actual calls; right?
- 13 A. I can't really see that. This is all Dr.
- 14 Bressi.
- Q. Right, but my question is, at this time in
- 16 2001 and continuing on --
- 17 A. Okay.
- 18 Q. -- until about 2006 or 2007, you had the
- 19 ability to write comments in detailing what had
- 20 actually occurred on your visits; right?
- 21 A. Yes.
- Q. And by the time you were seeing Dr. Gerber
- on Exhibit 23 on the right, you didn't have that
- 24 ability; right?

- 1 A. Right.
- 2 Q. So we would have no way of knowing what
- went on during those 76 calls because the company took
- 4 away your discretion and your ability to put in a
- 5 comment of what occurred on those calls; right?
- 6 A. Yes.
- 7 MR. MAIER: Objection. Form.
- 8 Q. (By Mr. Faes) So I'm going to switch
- 9 gears a little bit here. And we'll kind of go back to
- 10 Fentora. At some point during your time with Cephalon
- 11 and later Teva, you became aware that the company was
- 12 seeking an expanded indication for the Fentora product;
- 13 right?
- 14 A. Yes.
- 15 Q. You were aware that they had at least
- 16 asked the FDA for the indication of being able to
- 17 use -- excuse me -- being able to use Fentora for
- 18 breakthrough pain in patients without cancer, where it
- 19 was currently only indicated for patients with cancer;
- 20 right?
- 21 A. Yes.
- 22 Q. And you actually received -- well, strike
- 23 that. And you're aware that the FDA ultimately never
- 24 gave Cephalon or Teva permission to promote or sell

- 1 Fentora for noncancer pain; right?
- 2 A. Yes.
- MR. MAIER: Objection. Foundation.
- 4 Q. (By Mr. Faes) And you would have actually
- 5 received training and instruction from the company on
- 6 how to deal with questions from doctors such as can
- 7 Fentora be used in noncancer-related breakthrough pain;
- 8 right?
- 9 A. Yes.
- 10 Q. I'm going to hand you what's been marked
- 11 as Exhibit Number 26 to your deposition.
- 12 [Exhibit Teva-Kaisen-026
- marked for identification.
- MR. FAES: This is 24, Mike. Yeah, you
- 15 got it.
- 16 O. (By Mr. Faes) And this is a document
- 17 titled sales training and development, frequently asked
- 18 questions, FAQs, and responses. Do you see that?
- 19 A. Yes.
- Q. And you see down at the bottom it's
- 21 labeled FEN-2232, February 2011; right?
- 22 A. Yes.
- Q. So this would have been an approved
- 24 training material that would have been in effect at the

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1 company as of February of 2011; right?
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- MR. MAIER: Objection. Form, foundation.
- 3 A. Yes.
- 4 Q. (By Mr. Faes) If you can turn to Page 5
- 5 at this -- of this document. Under Question 5, it
- 6 gives a model question and an ACT targeted response;
- 7 right?
- 8 A. Yes.
- 9 Q. And the model question is can Fentora be
- 10 used in noncancer-related breakthrough pain; right?
- 11 A. Yes.
- 12 Q. And the targeted response is Fentora is
- only indicated in breakthrough pain for opioid-tolerant
- 14 patients with cancer. I can fill out a medical
- information request form, MIRF, if you have other --
- 16 questions about other types of pain; right?
- 17 A. Yes.
- 18 Q. And that's the response that you were
- 19 trained on by the company; right?
- 20 A. Yes.
- 21 Q. That's the response you were trained to
- 22 give?
- A. (Nodding "yes.")
- Q. And the company limited you to respond in

- 1 this manner; right?
- 2 A. Yes.
- Q. You wouldn't try to dissuade the doctor
- 4 from prescribing it for noncancer-related breakthrough
- 5 pain other than to repeat this targeted response
- 6 reiterating the indication; right?
- 7 A. Yes.
- 8 MR. MAIER: Objection. Form.
- 9 Q. (By Mr. Faes) You wouldn't, for example,
- 10 tell the physician that -- for example, that the
- 11 company had actually asked the FDA for that indication
- that he's asking about, but the FDA had told Cephalon
- 13 and the company no, they couldn't sell it for that
- 14 indication because they had serious concerns about
- misuse, abuse, overdose, and addiction; right?
- MR. MAIER: Objection. Form, foundation.
- 17 A. I would never have said that.
- 18 Q. (By Mr. Faes) Right. That's not a
- 19 response you were trained to give; right?
- 20 A. No.
- Q. You would have limited your response to
- the targeted response that's listed on this document;
- 23 right?
- 24 A. Yes.

- 1 Q. And it would be true if the doctor tried
- 2 to engage you further you would essentially have to say
- 3 look, Doctor. That's beyond my pay grade. I can fill
- 4 out a MIRF or I can direct you to the medical affairs
- 5 department; right?
- 6 MR. MAIER: Objection. Form, foundation.
- 7 A. Yes. Something like that.
- 8 Q. (By Mr. Faes) Right. So this medical --
- 9 the response includes that you can fill out a medical
- 10 information request form, or a MIRF, if the doctor has
- other -- questions about other types of pain; right?
- 12 A. Yes.
- Q. And that MIRF request could trigger the
- 14 company to potentially send the doctor an article or a
- 15 reprint of a study where Fentora or Actiq was used
- 16 outside of the approved indication for
- 17 noncancer-related breakthrough pain; right?
- 18 A. Yes.
- MR. MAIER: Objection. Form, foundation.
- Q. (By Mr. Faes) And you were trained in
- 21 fact that you couldn't submit too many MIRFs or medical
- 22 information requests? In fact, you couldn't -- they
- 23 told you you couldn't over-MIRF; right?
- MR. MAIER: Objection. Form, foundation.

- 1 A. I don't remember.
- Q. (By Mr. Faes) Okay. Let me hand you
- 3 what's been marked as Exhibit Number 27 to your
- 4 deposition.
- 5 [Exhibit Teva-Kaisen-027
- 6 marked for identification.
- 7 MR. FAES: I'm skipping one, Mike.
- 8 Q. (By Mr. Faes) So this is a document
- 9 titled sales bulletin, and it's to all sales -- all
- 10 field sales personnel, dated July 19th of 2007; right?
- 11 A. Yes.
- 12 Q. And so this would have been a document
- 13 received by you because you would have been a field
- 14 salesperson in January 19th of 2007; right?
- 15 A. Yes.
- Q. And if you turn to the second page of this
- document, there's a section entitled model sales call
- 18 behaviors; right?
- 19 A. Yes.
- 20 Q. And under Number 2 there's a question and
- 21 answer, and the question is, should we still complete
- 22 MIRFs for off-label questions? Is there a thing as
- 23 MIRFing too much? Do you see that?
- 24 A. Yes.

- Q. And the model response is the direct --
- 2 strike that. The model response is representatives
- 3 should definitely complete MIRFs for off-label
- 4 questions. This is the appropriate vehicle for
- 5 responding when a physician asks a question regarding
- 6 an off-label use of one of Cephalon products. There is
- 7 no thing -- no such thing as MIRFing too much. Do you
- 8 see that?
- 9 A. Yes.
- 10 Q. And this is training that you would have
- 11 received from Cephalon; right?
- 12 A. Yes.
- Q. And you would have followed their
- 14 instructions; right?
- 15 A. Yes.
- 16 Q. And so you were trained and told that
- there was no such thing as MIRFing too much; right?
- 18 A. Yes.
- 19 Q. And earlier in the day you remember we
- were talking about Cephalon speaker programs? Do you
- 21 remember that?
- 22 A. Yes.
- Q. Can you turn to Page 5 of this document
- 24 ending in 3852? The page numbers are in the upper

- 1 left-hand corner.
- A. Bottom?
- Q. Confused. Yeah, just give him a second.
- 4 A. No, I mean the bottom.
- 5 Q. Looking at Number 6. So on the bottom of
- 6 Page 5, one of -- there's another model question and
- 7 model answer, right, that you were trained on?
- A. (Nodding "yes.")
- 9 Q. And the question is, is it a compliance
- 10 violation if an attendee brings up off-label
- 11 discussions --
- 12 A. Uh-huh.
- Q. -- questions during a CSP, or Cephalon
- 14 speaker program? Is the sales representative required
- 15 to stop the discussion? Do you see that?
- 16 A. Yes.
- 17 Q. And the answer is speakers are permitted
- 18 to respond to off-label questions, but only at the end
- of a Cephalon speaker program during the Q & A portion
- of the program. Accordingly, such questions should be
- 21 deferred by the Cephalon speaker program speaker to the
- 22 end of the program and should not be answered --
- 23 addressed during the 20-minute on-label presentation.
- 24 Did I read that correctly?

- 1 A. Yes.
- Q. And that is consistent and is actually
- 3 training and instructions you got from your superiors
- 4 at the time; right?
- 5 A. Yes.
- 6 O. So it was in fact true that doctors
- 7 sometimes did and could ask questions about off-label
- 8 use of Actiq or Fentora following a Cephalon speaker
- 9 program; right?
- 10 A. When the speaker was finished.
- 11 Q. Right. So this was one way that a -- that
- the company could get within the confines of the law
- information regarding off-label use of the Actig or the
- 14 Fentora products to physicians; right?
- MR. MAIER: Objection. Form, foundation.
- 16 A. My understanding of that was to separate
- 17 medical -- sales -- medical from sales or whatever it
- 18 was. The speaker being the medical and the questions
- 19 were separate, not --
- 20 O. (By Mr. Faes) Right. I understand.
- 21 A. Not to mix the two.
- Q. I understand. At the end of the
- 23 program --
- A. Right.

- 1 Q. -- this was one way that the company
- 2 could have a speaker that they hired talk about
- 3 off-label use of Fentora or Actiq? They could give a
- 4 program and then they could answer questions about
- off-label use at the end of that program; right?
- 6 MR. MAIER: Objection. Form.
- 7 A. If they were answering questions, yes.
- Q. (By Mr. Faes) And you were taught that
- 9 that was perfectly legal; right?
- 10 A. Yes.
- MR. MAIER: Objection. Form.
- Q. (By Mr. Faes) And it was -- since it was
- 13 within the confines of the law, it was Cephalon's
- 14 policy that that was allowed; right?
- 15 A. Yes.
- MR. MAIER: Objection. Form, foundation.
- 17 Q. (By Mr. Faes) I'm going to hand you
- 18 what's been marked as Exhibit Number 28 to your
- 19 deposition.
- 20 [Exhibit Teva-Kaisen-028
- 21 marked for identification.]
- 22 Q. And this is another sales bulletin to --
- and it's to PCS, which would be pain care
- 24 specialists --

- 1 A. Uh-huh.
- 2 Q. -- dated April 15th of 2008. Do you see
- 3 that?
- 4 A. Yeah.
- 5 Q. And you were a pain care specialist --
- 6 A. Yes.
- 7 Q. -- at that time, right, so you would have
- 8 received this?
- 9 A. Yes.
- 10 Q. And the subject is WLF policy update. Do
- 11 you see that?
- 12 A. Uh-huh.
- Q. And it states this communication is being
- 14 sent to inform you of an update utilizing the WLF,
- 15 Washington Legal Foundation, reprints. In order to
- 16 better manage our business within today's ever-changing
- 17 regulatory environment, it has been decided that the
- distribution of all WLF reprints cease immediately and
- 19 all copies of these reprints in your possession should
- 20 be destroyed. Do you see that?
- 21 A. Yes.
- 22 Q. Should your physicians have a question or
- request information outside of the Fentora-approved
- indication, these articles will only be available

- 1 through a medical affairs response via an unsolicited
- 2 medical information request form or a MIRF; right?
- 3 A. Yes.
- 4 Q. So this is a communication that you would
- 5 have received at this time; right?
- 6 A. Yes.
- 7 Q. And you would have followed it and done
- 8 what the company instructed; right?
- 9 A. Yes.
- 10 Q. And as we talked about earlier, these WLF
- 11 reprints -- that's the Washington Legal Foundation;
- 12 right?
- A. Uh-huh.
- Q. And those included articles that discussed
- 15 Actiq and Fentora in some off-label indications; right?
- MR. MAIER: Objection. Form, foundation.
- 17 A. I don't remember what was in each of the
- 18 reprints.
- 19 Q. (By Mr. Faes) Is it true that at least
- 20 some of the Washington Legal Foundation articles
- 21 included the use of Fentora and Actiq in off-label
- 22 indications?
- 23 A. I don't remember.
- MR. MAIER: Objection. Form, foundation.

- 1 Q. (By Mr. Faes) But at least according to
- 2 this document, since the direction is now that these
- 3 articles will only be available through a MIRF request
- 4 from April 15th of 2008 going forward, you would read
- 5 that to mean that prior to that date you could
- 6 distribute those or leave those behind without a MIRF
- 7 request; right?
- 8 A. Yes.
- 9 MR. MAIER: Objection. Form, foundation.
- 10 Q. (By Mr. Faes) I'm going to hand you
- 11 what's been marked as Exhibit Number 29 to your
- 12 deposition.
- 13 [Exhibit Teva-Kaisen-029]
- marked for identification.]
- 15 A. This is too much for me right now.
- 16 O. We're on the homestretch. Trust me.
- 17 A. Yeah, because this is a lot for me right
- 18 now.
- 19 O. And this is an e-mail and attachment. And
- 20 I don't really need you to look at the e-mail other
- 21 than to note that the beginning of the e-mail notes
- 22 that it's a Actiq promotional guidelines PowerPoint,
- 23 and it says that the PCS would have implemented this
- 24 algorithm throughout the Actiq lifecycle. Do you see

- 1 that?
- 2 A. Yes. Thank you.
- 3 Q. So at least according to this e-mail,
- 4 the -- this algorithm or decision tree that we're going
- 5 to look at was implemented by the pain care sales
- force, which you were a member of, throughout the Actiq
- 7 lifecycle?
- 8 MR. MAIER: Objection. Form.
- 9 A. I'm not sure.
- 10 Q. (By Mr. Faes) Okay. Well, let's take a
- 11 look at it. So I really only want to ask you about one
- 12 specific part of this, and this is the second-to-last
- 13 page. And this is a decision tree and it starts at the
- 14 top, and for Actiq providers -- again, this is --
- 15 according to the e-mail is a decision tree utilized by
- 16 the pain sales care force (sic) throughout the Actiq
- 17 lifecycle.
- 18 It instructs the sales rep to open the
- 19 call with the following question. Do you have the
- 20 potential to treat patients with cancer pain? And if
- 21 you go to the right, if the physician responds no, it
- 22 goes down and instructs the rep to support by providing
- 23 Actiq safety and efficacy info, providing coupons and
- 24 welcome kits, and limiting calls to 12 times a year.

- 1 Do you see that?
- 2 A. I do.
- Q. Is that instruction that you would have
- 4 received when you were promoting Actiq during the
- 5 product lifecycle, that in response to the question, do
- 6 you treat patients with cancer pain, if the physician
- 7 responded no, you were still allowed to provide Actiq
- 8 coupons; right?
- 9 MR. MAIER: Objection. Form.
- 10 A. I don't remember this, but this is
- 11 written. Okay.
- 12 Q. (By Mr. Faes) Okay. So well, independent
- of this -- I'm just trying to refresh your memory.
- 14 A. Okay.
- 15 Q. Is it true that when you were promoting
- 16 Actiq during the product lifecycle --
- 17 A. Uh-huh.
- 18 Q. -- that you were trained that you could
- 19 ask the question or open the call with do you have the
- 20 potential to treat patients with cancer pain?
- 21 A. Yes.
- 22 Q. That was often how you started a call;
- 23 right?
- 24 A. Yes.

- 1 Q. And that was part of your training?
- 2 A. Yes.
- Q. And you followed that training and did
- 4 that quite often; right?
- 5 A. Yes.
- 6 Q. And then if the physician responds no, you
- 7 could still provide that physician with Actiq coupons
- 8 and a welcome kit; right?
- 9 A. Yes.
- 10 Q. And if the physician responded no at that
- 11 time, you were told by the company that you could still
- 12 call on that physician up to 12 times a year; right?
- 13 A. I don't remember that.
- Q. Do you have any reason to believe that
- 15 that's not true?
- 16 A. No.
- Q. And if that is the company's instructions
- that you could still call on a doctor that answered no
- 19 to that question, but you would -- you had to limit
- 20 your calls to 12 times a year, you would have followed
- 21 those instructions from the company; right?
- 22 A. Yes.
- Q. So I'm going to hand you what's been
- 24 marked as Exhibit Number 30 to your deposition.

- 1 [Exhibit Teva-Kaisen-030
- 2 marked for identification.]
- Q. And this is a PowerPoint and the title is
- 4 passion for performance impact. Do you see that?
- 5 A. I do.
- 6 Q. If you turn to the first page, this
- 7 appears to be a Great Lakes -- a POA agenda for a Great
- 8 Lakes meeting on June 7th and 8th of 2011. Do you see
- 9 that?
- 10 A. Yes.
- 11 Q. And it looks like your boss, Michael
- 12 Morreale, was leading a couple of the first sessions;
- 13 right?
- 14 A. Yes.
- Q. And you were in the Great Lakes region at
- this time reporting to Michael Morreale, so you would
- 17 have attended Great Lakes sales meetings; right?
- 18 A. Yes.
- 19 Q. Where did you usually have your Great
- 20 Lakes sales meeting?
- 21 A. They were anywhere. Anywhere within the
- 22 Great Lakes.
- Q. That's exactly what Ms. Gillenkirk says.
- 24 Nobody can remember where they met.

- 1 A. They weren't exciting venues. Trust me.
- Q. Where would -- I mean, where would you all
- 3 usually meet? Just at a hotel or rent a conference
- 4 room or something?
- 5 A. At a hotel in a city. I think we even had
- 6 one in Cleveland -- I'm not sure -- many years ago.
- 7 Q. Was there a city that you typically met
- 8 in?
- 9 A. Cincinnati a lot.
- 10 Q. Well, that's not very convenient for you.
- 11 Okay. So turning to Page 4 of this document. We've
- 12 got a slide titled top Fentora writers.
- A. We're not there yet.
- MR. BERG: Let's wait for it to come up.
- MR. FAES: I think it's July 24. Uh-huh.
- 16 They're not labeled, but I handwrote on all of my pages
- 17 so I could tell him what page to go to.
- 18 A. Okay.
- 19 Q. (By Mr. Faes) So this is a slide entitled
- 20 top Fentora writers, and this would have been
- 21 information that was presented at the meeting in 2011;
- 22 right?
- 23 A. Yes.
- Q. And if you look at -- I think there's four

- 1 columns here that are yours, Valerie McGinley. If I
- 2 can get Mike to highlight those. The first two are the
- 3 fourth and fifth one from the top.
- 4 A. Uh-huh.
- 5 MR. FAES: Actually, if you can highlight
- 6 them rather than call it out, because we're going to
- 7 have to go above that.
- 8 Q. (By Mr. Faes) So at this time in 2011, as
- 9 presented at this meeting, you had four of the top
- 10 Fentora writers presented on this list, including the
- 11 third highest and the fourth highest in the entire
- 12 Great Lakes region; right?
- 13 A. Yeah.
- Q. And your top prescriber was --
- 15 A. I can't look.
- 16 O. -- Sami Moufawad. Your second one was
- 17 Riad Laham. Your third one down was Jack Rutkowski,
- 18 and your fourth one was Sandra Hazra. Do you see that?
- A. Uh-huh.
- 20 O. So in at least one of your top four
- 21 prescribers, their primary specialty group is listed as
- 22 a primary care provider; right?
- 23 A. Yes.
- Q. So at this time in 2011, one of the top

- 1 four prescribers that you had of Fentora was not an
- 2 oncologist or a pain specialist; he was a primary care
- 3 provider; right?
- 4 A. Yes.
- 5 MR. MAIER: Objection. Form.
- 6 Q. (By Mr. Faes) And if you look at the
- 7 second column on Dr. Gregory Gerber, he was actually
- 8 the second highest prescriber at this time in the
- 9 entire Great Lakes region; right?
- 10 MR. MAIER: Objection. Foundation.
- 11 A. It's making me dizzy. That's why I'm
- 12 looking away. I was not calling on him in that time.
- 13 Q. (By Mr. Faes) Right. This is the time
- 14 that we talked about where Nicole Reese was calling on
- 15 him; right?
- 16 A. Right.
- Q. And you actually got him back -- this is
- in June. I think you got him back in early July, so
- 19 you got him back in your territory about a month after
- 20 this; right?
- A. Yeah.
- Q. And when you got him back he would have
- been the second highest prescriber of Fentora in the
- 24 entire Great Lakes region; right?

- 1 MR. MAIER: Objection. Form, foundation.
- 2 A. Yes.
- 3 Q. (By Mr. Faes) What were the circumstances
- 4 surrounding you getting Dr. Gerber back in your
- 5 territory? Why did that happen?
- 6 A. What year again?
- 7 O. This is 2011.
- 8 A. We realigned so many times. I can't
- 9 really remember.
- 10 Q. So it was a territory realignment?
- 11 A. Yeah.
- 12 Q. And you -- as a result of that you got the
- 13 second highest prescriber in the entire Great Lakes
- 14 region?
- 15 A. Yes.
- MR. MAIER: Objection. Form.
- 17 Q. (By Mr. Faes) And that -- getting the
- 18 second highest prescriber in the Great Lakes region
- 19 would have been good for you in terms of meeting your
- 20 sales performance goals; right?
- MR. MAIER: Objection. Form.
- A. Yes and no.
- Q. (By Mr. Faes) What do you mean by that,
- 24 yes and no? How is getting the second highest

- 1 prescriber not good for meeting your sales goal?
- 2 MR. MAIER: Objection. Form.
- 3 A. Because you have to keep him at that
- 4 level.
- 5 Q. (By Mr. Faes) Right. So you've got to
- 6 continually -- your sales goals are based on their
- 7 prior volume; right?
- 8 A. Yes.
- 9 Q. So in order to meet your sales goals
- 10 you've got to push to keep that doctor at or above that
- 11 level; right?
- 12 A. Yes.
- MR. MAIER: Objection. Form.
- Q. (By Mr. Faes) On the last page of this
- document under Fentora strategies, one of the Fentora
- 16 strategies is that Amrix should only be a mention call.
- 17 Do you see that?
- 18 A. Yes.
- 19 Q. And Amrix was the only other product that
- 20 you were responsible for detailing and promoting at
- 21 that time; right?
- 22 A. I don't remember. We -- I don't remember.
- Q. Well, and Amrix was a muscle relaxer;
- 24 right?

- 1 A. Yes.
- 2 Q. And did you come to understand that one of
- 3 the reasons you were instructed that a Fentora
- 4 strategy -- well, first of all, strike that and let me
- 5 start over. Would you agree with me that you were
- 6 generally instructed, consistent with this, that Amrix
- 7 should be a mention call, that if you detailed a doctor
- 8 for both products you generally wanted to detail the
- 9 Fentora first?
- 10 MR. MAIER: Objection. Form.
- 11 A. I don't remember.
- Q. (By Mr. Faes) Did you come to understand
- 13 that Amrix was a lower-priority target because the
- 14 Fentora prescription was worth much more to the company
- 15 than an Amrix prescription?
- MR. MAIER: Objection. Form, foundation.
- 17 A. I don't remember.
- 18 Q. (By Mr. Faes) You can set that aside.
- 19 [Discussion off the record.]
- THE VIDEOGRAPHER: We are going off the
- 21 record at 3:33 PM.
- [A brief recess was taken.]
- THE VIDEOGRAPHER: We are back on the
- 24 record at 3:40 PM.

- 1 Q. (By Mr. Faes) Ms. Kaisen, we're back on
- 2 the record after a short break. Are you ready to
- 3 proceed?
- 4 A. Yes.
- 5 Q. So I want to switch gears a little bit now
- 6 and talk about the FDA REMs or risk evaluation and
- 7 mitigation strategy program. Okay? At some point
- 8 during 2011, you become aware that the FDA was going to
- 9 require a REMs or a risk evaluation and mitigation
- 10 strategy program for Fentora going forward; right?
- MR. MAIER: Objection. Form.
- 12 A. If you say so.
- Q. (By Mr. Faes) Well, you understood that
- 14 there was -- at some point there was going to be --
- 15 A. Yes.
- 16 Q. -- a REMs program, and as part of that
- 17 REMs program, in order for a doctor and a patient to be
- 18 able to continue to receive Fentora going forward, both
- 19 the doctor and the patient would have to sign consent
- 20 forms indicating, among other things, that they
- 21 understood that the only indication for Fentora was for
- 22 breakthrough pain in opioid-tolerant patients with
- 23 cancer only; right?
- 24 A. Yes.

- 1 Q. I'm going to hand you what's been marked
- 2 as Exhibit Number 31 to your deposition. And this is
- 3 an e-mail dated July 21st of 2001. Do you see that?
- 4 [Exhibit Teva-Kaisen-031
- 5 marked for identification.]
- 6 A. Uh-huh.
- 7 Q. And it includes that it's been sent to
- 8 sales, PCS east region; right?
- 9 A. Yes.
- 10 Q. And that's kind of a group e-mail that you
- 11 would have received because you were in the east
- 12 region; right?
- 13 A. Yes.
- 14 Q. And it states that dear Fentora sales
- 15 team, on July 20th, 2011, we received approval of a
- 16 risk evaluation and mitigation strategy, or REMs, from
- 17 the U.S. Food and Drug Administration, FDA. And if you
- 18 go down it states now that we are in the approval
- 19 phase, we would ask you to continue to execute your POA
- 20 II strategy during the Fentora window of opportunity.
- 21 Do you see that?
- 22 A. Yes.
- Q. So the instructions from the company at
- this time is that a REMs or risk evaluation mitigation

- 1 strategy is coming, but you should continue to execute
- 2 your plan of action for Fentora during this window of
- 3 opportunity; right?
- 4 A. Yes.
- 5 Q. And it also directs at this time you do
- 6 not proactively discuss the approved Fentora and Actiq
- 7 REMs; right?
- 8 A. Yes.
- 9 Q. And that's instructions you would have
- 10 received at the time; right?
- 11 A. Yes.
- 12 Q. And you would have followed that
- instruction handed down by your superiors; right?
- 14 A. Yes.
- Q. And one of the other things that they
- instruct you to do is if you're asked about your
- 17 customers, about the Fentora or Actiq REMs, please
- 18 respond to all inquires in the following manner. And
- 19 the third thing they tell you to do is to remind your
- 20 customers that the approval of Fentora and the Actiq
- 21 REMs does not currently change their process for
- 22 Fentora writing. Do you see that?
- 23 A. Yes.
- Q. So essentially their instructions to you

- 1 at that time is for the time being, the REMs is coming,
- 2 your customers will eventually have to sign a consent
- 3 form, along with the customers, but for now doctors can
- 4 keep writing as usual; right?
- 5 A. Yes.
- 6 MR. MAIER: Objection. Form.
- 7 Q. (By Mr. Faes) And don't inform the
- 8 doctors that this is coming unless they ask; right?
- 9 A. Yes.
- 10 MR. MAIER: Objection. Form.
- 11 Q. (By Mr. Faes) And they referred to this
- time period as a window of opportunity; right?
- 13 A. Yes.
- Q. And they also instruct you, even though
- this REMs is coming, that until then you should
- 16 continue to work your plan in order to continue to
- 17 exceed our goal, which I assume is the company goal, of
- 18 1,100 prescriptions per week for the rest of 2011;
- 19 right?
- 20 A. Yes.
- 21 Q. So they essentially tell you to -- even
- 22 though the REMs is coming, to keep working to exceed
- 23 your goals -- your sales goals, keep trying to sell as
- 24 much Fentora as possible; right?

- 1 A. Yes.
- 2 MR. MAIER: Objection. Form.
- 3 Q. (By Mr. Faes) You can set that aside.
- 4 I'm going to hand you what's been marked as Exhibit
- 5 Number 32 to your deposition.
- 6 [Exhibit Teva-Kaisen-032]
- 7 marked for identification.]
- 8 Q. And this is a letter to the FDA -- or
- 9 strike that. This is a letter from the FDA to
- 10 Cephalon, and I'll represent to you that this date is
- 11 dated July 20th of 2011, which is the day before the
- 12 e-mail we just looked at, which is marked as Exhibit
- 13 Number 31.
- 14 A. Okay.
- Q. So this is the actual letter. Have you
- 16 ever seen this document before?
- 17 A. No.
- 18 Q. I'll represent to you that this is the
- 19 letter that the FDA sent to Cephalon informing them of
- 20 the REMs program, and then you got an e-mail about this
- 21 the day later, which we looked at as Exhibit Number 31.
- 22 Okay?
- 23 A. Okay.
- Q. And if you turn to the second page of this

- 1 document. It states that, in the middle of the page,
- 2 since Fentora was approved on September 25th of 2006,
- 3 we became aware of reports of deaths, including
- 4 patients treated for migraine headaches and chronic low
- 5 back pain. Do you see that?
- 6 A. I do.
- 7 Q. So essentially the FDA is saying that
- 8 they've become aware since Fentora was approved that
- 9 some people are being treated with Fentora off-label
- 10 and some of those people are dying; right?
- MR. MAIER: Objection. Form.
- 12 A. Yes.
- Q. (By Mr. Faes) And further down it says
- 14 pursuant to 50-1(f)(1) (sic), we've determined that
- 15 Fentora can remain on the market only if elements
- 16 necessary to assure safe use are required as part of
- 17 the REMs --
- 18 A. Thank you.
- 19 Q. -- to mitigate the risks of overdose,
- 20 abuse, addiction, and serious complication due to
- 21 medication errors that are listed in the labeling. Do
- 22 you see that?
- 23 A. Yes.
- Q. And the last sentence states these

- 1 elements will also assure proper patient selection and
- 2 dispensing of Fentora. Do you see that?
- 3 A. Yes.
- 4 Q. So essentially what this letter is saying
- is that one of the reasons for the REMs is, Number 1,
- 6 that people are using off-label and are dying, and
- 7 Number 2, the expanded use of Fentora in these
- 8 noncancer applications is giving them a concern of a
- 9 risk of overdose, abuse -- overdose, abuse, addiction,
- 10 and serious complications; right?
- MR. MAIER: Objection. Form, foundation.
- 12 A. I don't see overdose. Oh, there you go.
- 13 Yes.
- Q. (By Mr. Faes) And so if you look back at
- 15 Exhibit Number 31, first of all, it tells you as a
- 16 sales rep not to proactively bring it up.
- 17 A. Okay.
- 18 Q. This REMs; right?
- 19 A. (Nodding "yes.")
- Q. And it lists four things you do -- you
- 21 should do if a physician does bring it up; right?
- 22 A. Yes.
- Q. And you'd agree with me that nowhere in
- 24 that list of four things does it instruct you to inform

- 1 physicians that the REMs is being put into place
- 2 because the FDA has become aware of people using
- 3 Fentora off-label and dying, does it?
- 4 MR. MAIER: Objection. Form.
- 5 A. Simplify the question, please. I'm
- 6 getting brain dead. Sorry. Strike brain dead, please.
- 7 Q. (By Mr. Faes) So we're looking at Exhibit
- 8 Number 31, the --
- 9 MR. BERG: The e-mail the day --
- 10 Q. (By Mr. Faes) The e-mail --
- 11 A. Yes.
- 12 Q. -- that is informing you as the sales rep
- 13 that this REMs is coming; right?
- 14 A. Yes.
- Q. And if you look in the middle of the page
- 16 it says don't proactively bring up --
- 17 A. Yes.
- 18 Q. -- the REMs with your physician, but it
- 19 tells you four things to do if a doctor does bring it
- 20 up; right?
- 21 A. Yes.
- Q. And none of those four things include
- 23 telling the doctor that -- to tell the doctor that the
- 24 REMs has -- one of the reasons the REMs is coming out

- 1 is because the FDA has become aware that certain people
- 2 are using Actiq off -- or sorry -- that certain people
- 3 are using Fentora off-label and are dying; right?
- 4 MR. MAIER: Objection. Form.
- 5 A. Yes.
- 6 Q. (By Mr. Faes) And there's nothing in here
- 7 instructing you as a sales rep to tell doctors that one
- 8 of the reasons the Fentora REMs is coming out is
- 9 because the FDA has serious concerns about overdose,
- 10 abuse, addiction, and serious complications from
- 11 Fentora; right?
- MR. MAIER: Objection. Form, foundation.
- 13 A. Yes.
- 14 Q. (By Mr. Faes) You can set that aside. So
- 15 I'm going to hand you what's been marked as Exhibit 33
- 16 to your deposition.
- 17 [Exhibit Teva-Kaisen-033
- marked for identification.
- MR. FAES: And Mike, I've skipped to 35.
- 20 Cut out another one.
- Q. (By Mr. Faes) So this is an e-mail
- 22 string. Exhibit 35 is an e-mail string from you to
- your boss, Michael Morreale. And let's actually start
- 24 at the beginning of this e-mail string. It goes bottom

- 1 to top on August 3rd of 2013.
- And it's an e-mail from to you Michael and
- 3 the subject is forward, prescribing opioid guidelines,
- 4 and you state Michael, FYI, the State Medical Board of
- 5 Ohio has instituted the attached guidelines for
- 6 prescribing opioids for the treatment of chronic
- 7 nonterminal pain, 80 milligram of a morphine equivalent
- 8 daily dose, MED trigger point. It has gone into effect
- 9 as of July 1st, 2013. Several of my HCPs have brought
- 10 this to my attention and have been removing patients
- 11 from our product. Can you please advise me how to
- 12 proceed? Do you see that?
- 13 A. I do.
- Q. And this is an e-mail that would have been
- 15 written by you; right?
- 16 A. Yes.
- 17 Q. And the product that health care providers
- 18 have been removing their patients from that you're
- 19 referencing is Fentora; right?
- 20 A. Yes.
- 21 Q. And you're reaching out to your manager,
- 22 your direct report, for advice to what to do about this
- 23 situation because you're losing customers and losing
- 24 sales; right?

- 1 A. Uh-huh.
- Q. And the response from your boss, Michael
- 3 Morreale, is Val, use your relationships and have some
- 4 conversations with your thought leaders on these
- 5 guidelines to find out what their thoughts on it -- to
- 6 find out their thoughts on it and help you develop a
- 7 plan to deal with it. You need to consistently educate
- 8 and remind your writers on why Fentora is the best
- 9 option for their breakthrough cancer pain patients.
- 10 You mentioned that you have lost several
- 11 patients because of these guidelines. Who were the
- 12 physicians and what did they have to say about it and
- 13 what med did they switch them to? Let me know what you
- 14 find out from your thought leaders. Michael Morreale.
- 15 Do you see that?
- 16 A. Yes.
- 17 Q. So kind of not a very useful answer;
- 18 right?
- 19 A. No comment.
- 20 Q. So basically what Michael is saying is he
- 21 doesn't know what to do and you should reach out to
- 22 some other people to try to figure this situation out;
- 23 right?
- 24 A. Yes.

- 1 MR. MAIER: Objection. Form, foundation.
- Q. (By Mr. Faes) And you reply in response
- 3 to his question that, hi, Dr. Chen, Dr. Poje, and Dr.
- 4 Goddard; right?
- 5 A. Yes.
- 6 Q. And those are the doctors that are
- 7 concerned about it and taking their patients off
- 8 Fentora; right?
- 9 A. Their cancer patients, yes.
- 10 Q. And you say they didn't switch them to
- 11 anything. They are decreasing, weaning them, and then
- 12 not prescribing short-acting and just using the long so
- that they are below the 80 milligram trigger.
- 14 A. Yes.
- 15 Q. Thank you for your input. Val.
- 16 A. Yes.
- Q. And so let me mark as Exhibit --
- 18 [Exhibit Teva-Kaisen-034]
- marked for identification.]
- Q. I'm going to hand you what's been marked
- 21 as Exhibit Number 34 to your deposition. That's yours.
- 22 That's his. And then I'll also mark Exhibit Number 35.
- 23 [Exhibit Teva-Kaisen-035
- 24 marked for identification.

- 1 A. Here we go.
- Q. Now, Exhibit Number 34 -- that's the
- 3 actual Ohio prescribing guidelines that you were
- 4 discussing in that prior e-mail; right?
- 5 A. Yes.
- 6 Q. And the title of this document is fighting
- 7 prescription drug abuse, Rx prescribing guidelines. Do
- 8 you see that?
- 9 A. Yes.
- 10 Q. So the intent of this from the Ohio opioid
- 11 action team is to fight prescription drug abuse; right?
- 12 A. Yes.
- Q. And so if you look down from the third
- 14 from the top, it says that the new opioid prescribing
- 15 quidelines recommend that 80 milligrams MED for more
- than three months for patients with chronic nonterminal
- pain should trigger the prescriber to reevaluate the
- 18 effectiveness and safety of the patient's pain
- 19 management plan; right?
- 20 A. Yes.
- Q. And so basically what this is saying is
- that if you're going above the 30 milligrams MED in a
- 23 single day for more than three months --
- 24 A. I don't see 30.

- 1 Q. I'm sorry?
- 2 A. I don't see 30.
- 3 Q. Sorry. So basically what this is saying
- 4 is that if you go above 80 milligrams MED for more than
- 5 three months with a patient with chronic nonterminal
- 6 pain, you should reevaluate your treatment plan for
- 7 that patient because it might not be safe; right?
- 8 A. Right.
- 9 MR. MAIER: Objection. Form, foundation.
- 10 Q. (By Mr. Faes) That's your understanding
- 11 from this document at this time; right?
- 12 A. Yes.
- MR. MAIER: Objection.
- Q. (By Mr. Faes) And so you knew that in
- 15 order to be -- strike that. In order to be a proper
- 16 candidate for Fentora you had to be an opioid-tolerant
- 17 patient; right?
- 18 A. Yes.
- 19 Q. And in order to be an opioid-tolerant
- 20 patient you needed to be on 60 milligrams MED to be
- 21 qualified to be an opioid-tolerant patient; right?
- 22 A. Yes.
- 23 Q. So in order to take Fentora you've already
- 24 got to be on 60 milligrams MED of some long-term-acting

- 1 opioid, and the smallest dose to Fentora is 100
- 2 milligrams; right?
- MR. MAIER: Objection. Form.
- 4 A. I'm sorry. 60 milligrams of morphine
- 5 equivalent of short-acting, and then a 25 mic patch of
- 6 long-acting or higher equivalent. Your question was --
- 7 go back to his question. You were already on 60
- 8 milligrams of some long-term opioid, and the smallest
- 9 dose -- okay.
- 10 Q. (By Mr. Faes) Let me try and start over
- and see if I can ask a better question; okay?
- 12 A. Just -- thank you.
- 13 Q. So the smallest dose of Fentora is 100
- 14 micrograms; right?
- 15 A. Yes.
- 16 Q. And if you look at the conversion chart
- 17 marked as Exhibit 35 and you look at the conversion for
- 18 fentanyl buccal or SL tablets, the conversion is .13,
- 19 which would mean the smallest dose of Fentora at 100
- 20 micrograms would be 30 milligrams equivalent MED;
- 21 right?
- MR. MAIER: Objection. Form.
- 23 A. Yes.
- Q. (By Mr. Faes) So essentially in order to

- 1 take Fentora in accordance with these new Ohio
- 2 guidelines, the most Fentora that you could take in a
- 3 day would be only one 100 microgram tab; right?
- 4 MR. MAIER: Objection. Form.
- 5 A. I'm not sure. I'm getting dizzy with the
- 6 numbers.
- 7 Q. (By Mr. Faes) Okay. So -- but at any
- 8 rate, you'd agree that a lot of your doctors were
- 9 taking off -- taking their patients off Fentora
- 10 altogether and only keeping them on long-acting opioids
- 11 because they felt that they couldn't prescribe Fentora
- 12 and stay within the new guidelines; right?
- 13 A. The cancer patients.
- MR. MAIER: Objection. Form.
- 15 A. Yes.
- Q. (By Mr. Faes) So let me hand you what's
- been marked as Exhibit Number 36.
- 18 [Exhibit Teva-Kaisen-036]
- marked for identification.]
- 20 O. And this is an e-mail from you down at the
- 21 bottom to another Ohio sales rep, Corinne Gillenkirk,
- 22 asking about this issue; right?
- 23 A. Yes.
- Q. And you say FYI, you probably know this

- 1 already, but I attached a copy for you. I've had some
- 2 management physicians stop writing due to the new Ohio
- 3 guidelines in Ohio. Let me know your thoughts. Right?
- 4 A. Yes.
- 5 Q. And this is you reaching out to another
- 6 fellow sales rep trying to find a solution to this
- 7 problem; right?
- 8 A. Yes.
- 9 Q. And this is essentially -- one of the
- 10 reasons you did this probably was because your boss
- 11 didn't give you a very useful answer; right?
- MR. MAIER: Objection. Form.
- Q. (By Mr. Faes) Is that true?
- 14 A. I don't know why I did it back then, but
- 15 it could be.
- Q. And her response is yes, a physician of
- mine gave me a copy a while back. He's the only one
- 18 who's voiced concern over the 80MG morphine equivalent
- 19 dose. I don't bring it up otherwise. Right?
- 20 A. Yes.
- 21 Q. So her -- kind of her advice is she hasn't
- 22 had much problem with it, but she doesn't bring it up
- 23 if the doctor doesn't; right?
- MR. MAIER: Objection. Form, foundation.

- 1 A. Okay.
- Q. (By Mr. Faes) Is that true?
- MR. MAIER: Same objection.
- 4 A. It says so.
- 5 Q. (By Mr. Faes) And is that your
- 6 understanding of what she was telling you?
- 7 MR. MAIER: Same objection.
- 8 A. My understanding, yes.
- 9 Q. (By Mr. Faes) Just three left and we're
- 10 done. I'm going to hand you what's been marked as
- 11 Exhibit Number 37 to your deposition.
- 12 [Exhibit Teva-Kaisen-037
- marked for identification.
- Q. And this is an e-mail dated May 30th of
- 15 2014, and again, this is from you to your boss, Michael
- 16 Morreale. And if you look halfway down it states
- 17 challenges. The Cleveland Clinic is not wanting their
- 18 physicians to write TIRFs. Some have not renewed their
- 19 REMs. They are encouraging blocks. Do you see that?
- 20 A. Yes.
- 21 Q. And that was an issue that you were
- 22 experienced at the time that you passed on to your
- 23 boss, that some doctors at this time in 2014 basically
- 24 didn't want to sign the REMs consent form to continue

- 1 to sell -- to continue to be able to write Fentora;
- 2 right?
- MR. MAIER: Objection. Form.
- 4 A. They did not want to write TIRFs.
- 5 Q. (By Mr. Faes) Right. And TIRF --
- A. It had nothing to do with the REMs.
- 7 O. Huh?
- 8 A. It had nothing to do with the REMs. They
- 9 just didn't want to -- it says some have not renewed
- 10 because they don't want to write any more short-acting.
- 11 Q. Okay. And was that because of the Ohio
- 12 prescribing guidelines that we just talked about?
- 13 A. I don't know.
- 14 MR. MAIER: Objection. Foundation.
- 15 A. I don't remember.
- Q. (By Mr. Faes) Well, if you go --
- 17 A. On here it says -- yeah.
- 18 Q. So you just don't remember the reason why?
- 19 A. It says it right here now.
- Q. Right. So it says that the reason is the
- 21 Ohio prescribing guidelines on opioids do not prescribe
- over 80 milligram or equivalent per patient per day.
- 23 The exception is cancer. However, physicians have
- 24 expressed that they don't want to write that much for

- 1 any patient, including cancer patients.
- 2 A. Yes.
- 3 Q. The DEA has visited several physicians.
- 4 Certain internal medicine physicians have been warned
- 5 for not giving up their patients to pain management
- 6 after 12 weeks. Physicians in my territory are
- 7 decreasing their opioids tremendously and fear
- 8 increasing their cancer patients.
- 9 MR. MAIER: Object --
- 10 A. Including --
- 11 Q. (By Mr. Faes) Sorry. Including their
- 12 cancer patients.
- 13 A. Yes.
- Q. So this reflects that these Ohio
- 15 prescription guidelines that were intended to fight
- 16 prescription drug abuse are still continuing to be an
- issue that you're reporting to your superiors in May of
- 18 2014; right?
- MR. MAIER: Objection. Form.
- 20 A. Drug abuse? I mean, give me a better
- 21 question than that.
- 22 Q. (By Mr. Faes) So these -- this reflects
- 23 that these -- that the new Ohio -- strike that. Let me
- 24 start over. This reflects that the new Ohio

- 1 prescription guidelines which recommend limiting
- 2 patients to 80 milligrams MED are continuing to be a
- 3 factor that you were reporting as an issue to your
- 4 boss, Michael Morreale, at this time; right?
- 5 MR. MAIER: Objection. Form.
- 6 A. Including their cancer patients.
- 7 Q. (By Mr. Faes) So is the answer to my
- 8 question yes --
- 9 A. Yes.
- 10 Q. -- that this continues to be an issue?
- 11 A. Yes.
- 12 Q. And as we discussed, the purpose of those
- 13 guidelines is to fight prescription drug abuse; right?
- MR. MAIER: Objection. Foundation.
- 15 A. These are cancer patients.
- Q. (By Mr. Faes) I understand. But my
- 17 question is, you understand that the Ohio prescribing
- 18 guidelines were put in place specifically to fight
- 19 prescription drug abuse; right?
- 20 A. Sure.
- 21 Q. And at this time this is really affecting
- the sales in your territory; right?
- MR. MAIER: Objection. Foundation, form.
- A. It's affecting my cancer patients.

- 1 Q. (By Mr. Faes) And it's affecting your
- 2 sales as well; right?
- 3 A. Which affects sales. Yes.
- 4 Q. And when your sales are affected, that
- 5 affects your income as well; right?
- 6 MR. MAIER: Objection. Form.
- 7 A. Yes. It's all about the patients.
- Q. (By Mr. Faes) I'm going to hand you
- 9 what's been marked as Exhibit Number 38 to your
- 10 deposition.
- 11 [Exhibit Teva-Kaisen-038
- marked for identification.]
- Q. Do I only have one copy? I think I only
- 14 have one copy. So I only have one copy, so I'm going
- to have to give you mine and I'll look at the one on
- 16 the screen.
- 17 A. Okay.
- 18 Q. This is -- I'm handing you what I've
- 19 been -- what's marked as Exhibit Number 38. And you
- 20 can go to the second page of this, which is where the
- 21 e-mail starts. It starts with an e-mail -- well, it's
- 22 on the previous page. I think it's to you and then it
- 23 carbon copies Mr. Morreale, your boss, and your boss's
- 24 boss, Randy Spokane. Do you see that?

- 1 A. Yes.
- Q. And -- yeah, it's to you. So let's go
- 3 back to the second page. And it states on November
- 4 2nd, 2012, you recorded a Fentora call to the following
- 5 health care provider. Debbie Macko. And it says this
- 6 HCP is on the do-not-compensate list for Fentora.
- 7 Please document an explanation for this call and
- 8 forward to your region manager -- region manager. Do
- 9 you see that?
- 10 A. Yes.
- 11 Q. So this would have been an e-mail that you
- 12 received; right?
- 13 A. Yes.
- Q. And was this part of an automated system
- whereby if there was a doctor that you called on that
- 16 you were not supposed to, you would get an automated
- message?
- MR. MAIER: Objection. Form.
- 19 A. I don't remember, but --
- Q. (By Mr. Faes) Well, let's go to the first
- 21 page of this. And it says on November 4th, 2012,
- 22 Valerie Kaisen wrote, hi, Michael. The pain center at
- 23 South Pointe changed their policy. They are having
- lunches again. I cannot change them back to compensate

- 1 on the iPad. Thank you.
- A. Where are you? Oh, okay. Got it. Sorry.
- Q. You see that?
- 4 A. Yeah.
- 5 Q. So that was your response at the time?
- 6 A. Yes.
- 7 Q. And then if you look prior to that --
- 8 A. Okay. What's your question?
- 9 Q. So I'm just going through the e-mail. And
- 10 then your boss writes back, Debbie Macko is on the DNC
- list, so you can't make calls on her. Please explain
- 12 why you made a call on her. Right?
- 13 A. Yes.
- Q. So this is your boss saying that she's on
- the DNC list and you're not supposed to call on her;
- 16 right?
- 17 A. Yes.
- 18 Q. And you reply I did not put her on the
- 19 do-not-compensate list. They stopped having lunches
- 20 about 18 months ago. A couple of months ago they
- 21 changed to being able to accept food. Also, she is the
- 22 nursing administrator of pain management. I'm sorry.
- 23 I will not call on her or feed her going forward.
- 24 Thanks. Valerie Kaisen. Right?

- 1 A. Okay.
- 2 Q. So that was the response you would have
- 3 given Michael at the time --
- 4 A. Yes.
- 5 Q. -- that you didn't realize she was on the
- 6 DNC list and wouldn't call her again; right?
- 7 A. Yes.
- Q. And your boss writes back Val, this has
- 9 nothing to do with the HCP and the Sunshine Act.
- 10 Teva/Cephalon deemed Debbie Macko as a do not
- 11 compensate, AKA do not call, meaning the health care
- 12 provider is not appropriate to make calls based on her
- 13 specialty. Do you see that?
- 14 A. Yes.
- O. So basically Michael is telling you that
- 16 this doctor isn't an appropriate doctor for you to be
- 17 calling on; right?
- 18 A. Right.
- Q. And you reply I'm sorry. I put on a call
- 20 to Deb Macko. I didn't realize she was on the list. I
- 21 will not call on her again. Right?
- 22 A. Yes.
- Q. So I'm going to hand you what's been
- 24 marked as Exhibit Number 39 to your deposition.

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1 [Exhibit Teva-Kaisen-039
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- 2 marked for identification.]
- 3 Q. And this is an e-mail about three months
- 4 later dated February 11th of 2013. And again, if you
- 5 look at where the e-mail begins --
- 6 MR. FAES: This is the next document, 40.
- 7 It's 40.
- 8 Q. (By Mr. Faes) If you look at the document
- 9 where the e-mail string begins. It starts on February
- 10 10th of 2013, and again it's to you and your boss and
- 11 your boss's boss, Michael Morreale and Randy Spokane,
- 12 and again you're getting a message that on February
- 13 8th, 2013, you recorded a Fentora call again to Debbie
- 14 Macko; right?
- 15 A. Yes.
- 16 Q. And your response again is, three months
- 17 later, Michael, Debbie Macko is on the Cleveland Clinic
- 18 south pain center, and that you didn't know that she
- 19 was on the DNC list; right?
- 20 A. Yes.
- 21 Q. And you respond that she didn't know --
- that she hasn't been on the list before; right?
- 23 A. Yes.
- Q. And this is despite having called on her

- 1 three months earlier and receiving a similar message
- 2 that she was on the DNC list; right?
- A. I don't remember. It's here, but I don't
- 4 remember.
- 5 Q. Well, do you have any reason to dispute
- 6 the authenticity of these documents that we've looked
- 7 at?
- 8 A. No.
- 9 MR. FAES: Okay. I think that's all the
- 10 further questions I have at this time, subject to any
- 11 follow-up from any other counsel that's going to
- 12 question.
- MR. MAIER: Yeah.
- MR. FAES: I don't think Ms. Jain has any
- 15 questions. Is that right?
- MS. JAIN: That's correct.
- 17 MR. MAIER: I have five minutes of
- 18 questions.
- 19 A. Yes.
- 20 [Discussion off the record.]
- 21 QUESTIONS BY MR. MAIER:
- Q. So I just have hopefully about five
- 23 minutes of questions for you, and to keep them short
- 24 we're going to bounce around a little bit on topics,

- 1 but we won't spend long on any one of them. So did the
- 2 FDA-approved labels for Actiq and Fentora include their
- 3 indications?
- 4 MR. FAES: Object to form.
- 5 A. You're going to have to talk slower, but
- 6 yes.
- 7 Q. Do the FDA-approved labels for Actiq and
- 8 Fentora include information about the risks associated
- 9 with them?
- MR. FAES: Object to form.
- 11 A. Yes.
- 12 Q. (By Mr. Maier) What were some of the
- risks that were on the label, if you remember?
- 14 A. Now we're going back. Bradycardia. I
- 15 can't remember, you guys, right now.
- 16 O. That's fine. But it's fair to say that
- 17 you recall that the risks that were identified by the
- 18 FDA were on the label for each of those drugs?
- 19 A. Yes.
- 20 MR. FAES: Object to form.
- Q. (By Mr. Maier) We just spoke about the
- 22 REMs program. Do you remember that?
- 23 A. Yes.
- Q. So do you remember if there was an

- 1 FDA-approved REMs program for all transmucosal
- 2 immediate-release fentanyl products?
- 3 A. Yes.
- 4 Q. Is that the same thing as the REMs program
- 5 that we talked about in that one e-mail from 2011, or
- 6 do you remember if there was a Fentora Actiq REMs
- 7 program and then TIRF REMs after?
- 8 MR. FAES: Object to form.
- 9 A. I don't remember, but I think they were
- 10 all the same time. They were all the same time.
- 11 Q. (By Mr. Maier) But once there was a REMs
- 12 program in place, doctors were required to enroll
- 13 before they could prescribe Fentora; is that right?
- 14 A. Yes.
- Q. And patients were required to enroll
- 16 before they could receive Fentora?
- 17 A. Yes.
- 18 Q. And that REMs program also included
- 19 information about the risks associated with Fentora and
- 20 Actiq?
- 21 MR. FAES: Object to form.
- 22 A. Yes.
- Q. (By Mr. Maier) Did you ever promote Actiq
- 24 or Fentora off label?

- 1 A. No.
- 2 MR. FAES: Object to form.
- 3 Q. (By Mr. Maier) Were you ever told to
- 4 promote Actiq or Fentora off label?
- 5 MR. FAES: Object to form.
- 6 A. No.
- 7 Q. (By Mr. Maier) Did you ever use
- 8 promotional material when you were promoting Actiq and
- 9 Fentora that you understood to contain anything that
- 10 would constitute off-label promotion of either drug?
- MR. FAES: Object to form.
- 12 A. No, I don't remember. No.
- Q. (By Mr. Maier) Earlier today you were
- 14 asked about physicians prescribing medication off
- 15 label. Do you remember that?
- 16 A. Yes.
- Q. Who makes the decision about whether an
- 18 off-label use of a prescription is medically
- 19 appropriate?
- MR. FAES: Object to form.
- 21 A. The physician.
- Q. (By Mr. Maier) Do you remember when we
- 23 talked about MIRFs earlier?
- 24 A. Yes.

- 1 Q. When you submitted a MIRF, it was medical
- 2 affairs who dealt with it, you said, I believe?
- 3 A. Yes.
- 4 Q. Was medical affairs part of marketing?
- 5 A. No.
- 6 MR. FAES: Object to form.
- 7 Q. (By Mr. Maier) So to your knowledge did
- 8 Cephalon or Teva marketing personnel respond
- 9 substantively to any questions about off-label use?
- MR. FAES: Object to form.
- 11 A. Never.
- 12 Q. (By Mr. Maier) You were asked earlier
- 13 about what you were trained to say if a doctor said
- 14 that they did not treat cancer patients. Do you
- 15 remember that?
- 16 A. Yes.
- 17 Q. Those doctors who said that they didn't
- 18 have cancer patients could have had cancer patients in
- 19 the future; correct?
- MR. FAES: Object to form.
- 21 A. Yes.
- Q. (By Mr. Maier) And in your experience,
- would it have been helpful for them to be prepared if a
- 24 cancer patient who might benefit from Actiq and Fentora

- 1 and been a good candidate for on-label use come into
- 2 their office?
- 3 A. Yes.
- 4 MR. FAES: Object to form.
- 5 Q. (By Mr. Maier) Did you receive compliance
- 6 training at Teva and Cephalon?
- 7 A. Yes.
- 8 Q. Did it inform you of your obligation to
- 9 promote products for only labeled indications?
- 10 A. Yes.
- 11 Q. How often did those occur?
- 12 A. I don't remember, but it seemed like all
- 13 the time.
- Q. Were they mandatory?
- 15 A. Oh, yeah.
- MR. MAIER: That's all I have. Thank you.
- 17 A. Thank you. Whew.
- 18 QUESTIONS BY MR. FAES:
- 19 Q. Earlier -- I just have one or two
- 20 follow-up questions. Earlier defense counsel was
- 21 asking you who makes the decision about whether an
- off-label use for a product is appropriate. Do you
- 23 remember that question?
- 24 A. Who -- I guess -- say it again.

- 1 Q. Yes. Earlier defense counsel was asking
- 2 you a question about who makes the decision whether or
- 3 not an off-label use for a product is appropriate. Do
- 4 you remember that?
- 5 A. Yes.
- 6 Q. And you answered that it's the
- 7 physician --
- 8 A. Yes.
- 9 Q. -- that makes that decision; right? And
- 10 you'd agree with me that the physician, in order to
- 11 make the appropriate decision about whether to use a
- 12 product off label, needs to have all the appropriate
- 13 information; right?
- MR. MAIER: Objection. Form, foundation.
- 15 A. That's up to the physician to make the
- 16 decision.
- Q. (By Mr. Faes) But in order to make -- you
- 18 would agree with me that in order for the doctor to
- make an informed decision, he needs to have all of the
- 20 relevant information about the risks and benefits of
- 21 the product; right?
- 22 A. Yes.
- MR. MAIER: Objection. Form.
- Q. (By Mr. Faes) And that would include

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information such as whether the FDA had serious
 1
    concerns about abuse, misuse, overdose, and addiction
 2
 3
     in the patient population he's considering treating;
 4
    right?
 5
            Α.
                  Yes.
 6
                  MR. MAIER: Objection. Form, foundation.
 7
                 (By Mr. Faes) And that would include
            O.
 8
     information regarding deaths that had occurred while
    patients were on that drug for the indication that he's
 9
10
    considering; right?
11
                  THE WITNESS: Yes.
12
                  MR. MAIER: Same objection.
13
                  MR. FAES: That's all the further
14
    questions I have.
15
                  MS. FRANCIS: No questions.
16
                  MR. MAIER: That's it.
17
                  MR. BERG: Okay.
                  THE VIDEOGRAPHER: We are going off the
18
19
    record at 4:20 PM.
20
                  [Discussion off the record.]
21
                  MR. BERG: She'll waive.
22
23
                       [SIGNATURE WAIVED.]
24
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1	CERTIFICATE
2	
3	I, JOHN ARNDT, a Certified Shorthand
4	Reporter and Certified Court Reporter, do hereby
5	certify that prior to the commencement of the
6	examination, VALERIE KAISEN was sworn by me to testify
7	the truth, the whole truth and nothing but the truth.
8	I DO FURTHER CERTIFY that the foregoing is a
9	true and accurate transcript of the proceedings as
10	taken stenographically by and before me at the time,
11	place and on the date hereinbefore set forth.
12	I DO FURTHER CERTIFY that I am neither a
13	relative nor employee nor attorney nor counsel of any
14	of the parties to this action, and that I am neither a
15	relative nor employee of such attorney or counsel, and
16	that I am not financially interested in this action.
17	
18	
19	
20	JOHN ARNDT, CSR, CCR, RDR, CRR
21	CSR No. 084-004605
22	CCR No. 1186
23	
24	